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GUIDE TO THE REGULATION OF TOXIC CHEMICALS IN MASSACHUSETTS WATERS

December 1990



THE MASSACHUSETTS DEPARTMENT OF
ENVIRONMENTAL PROTECTION

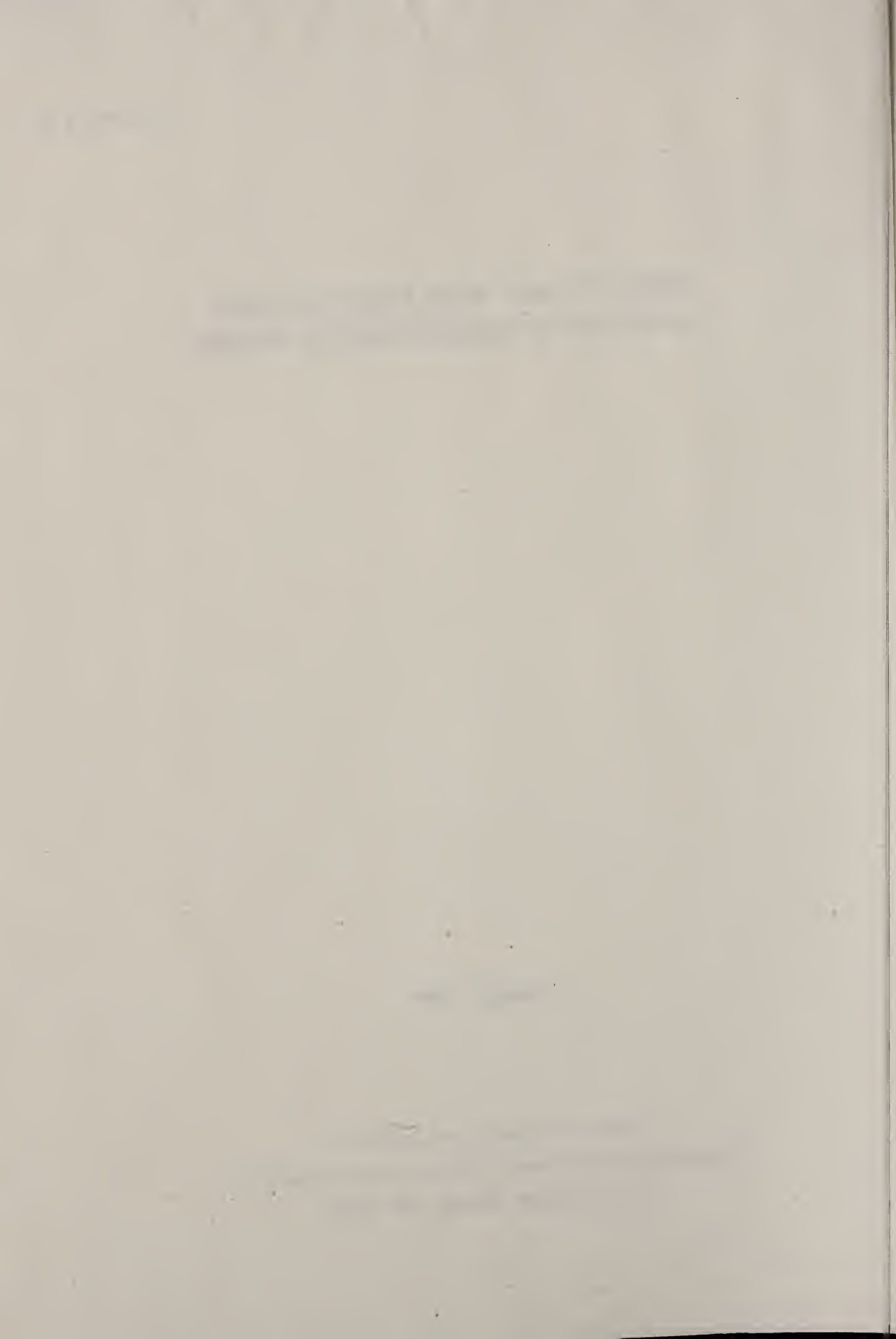
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**GUIDE TO THE REGULATION OF TOXIC
CHEMICALS IN MASSACHUSETTS WATERS**

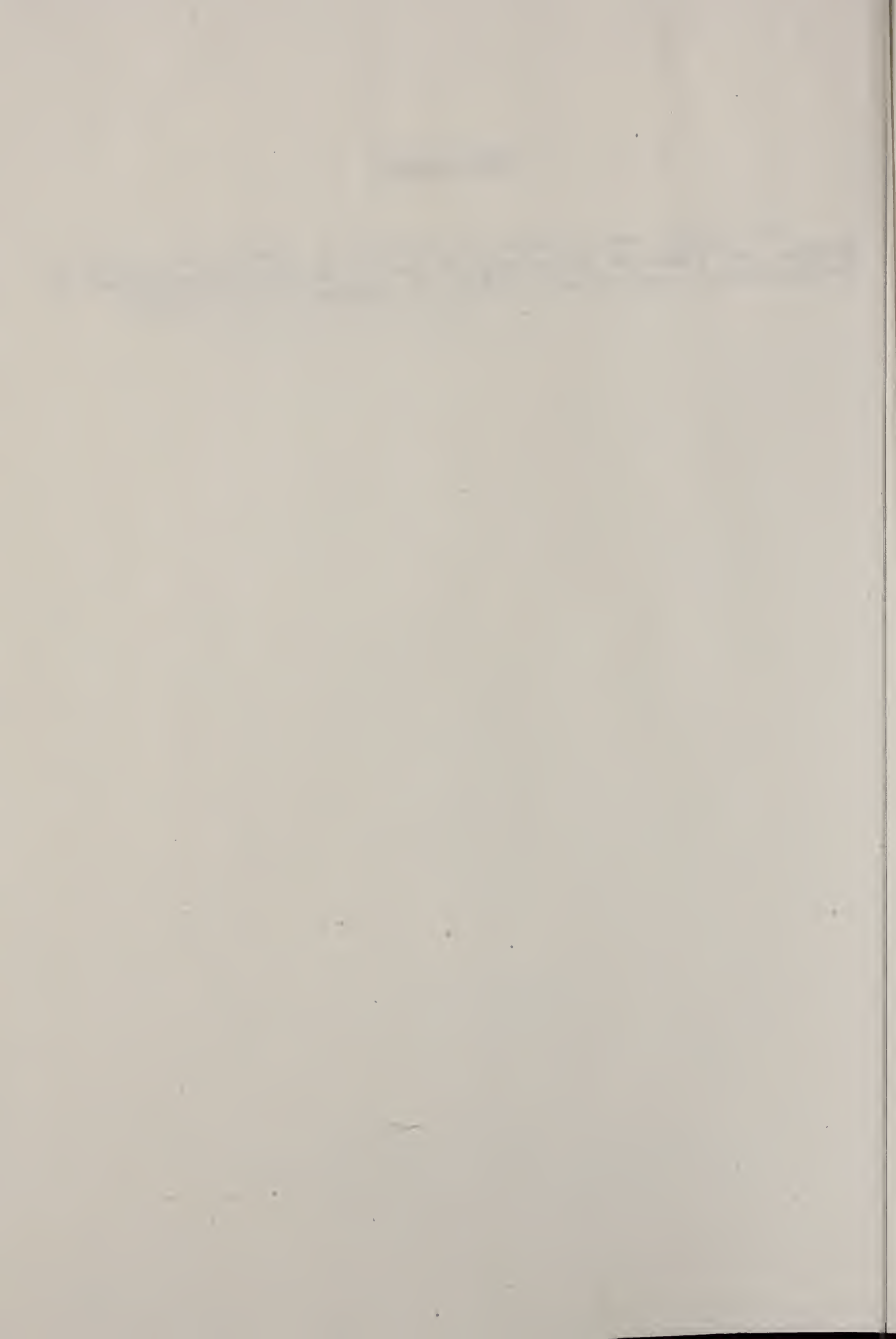
December 1990

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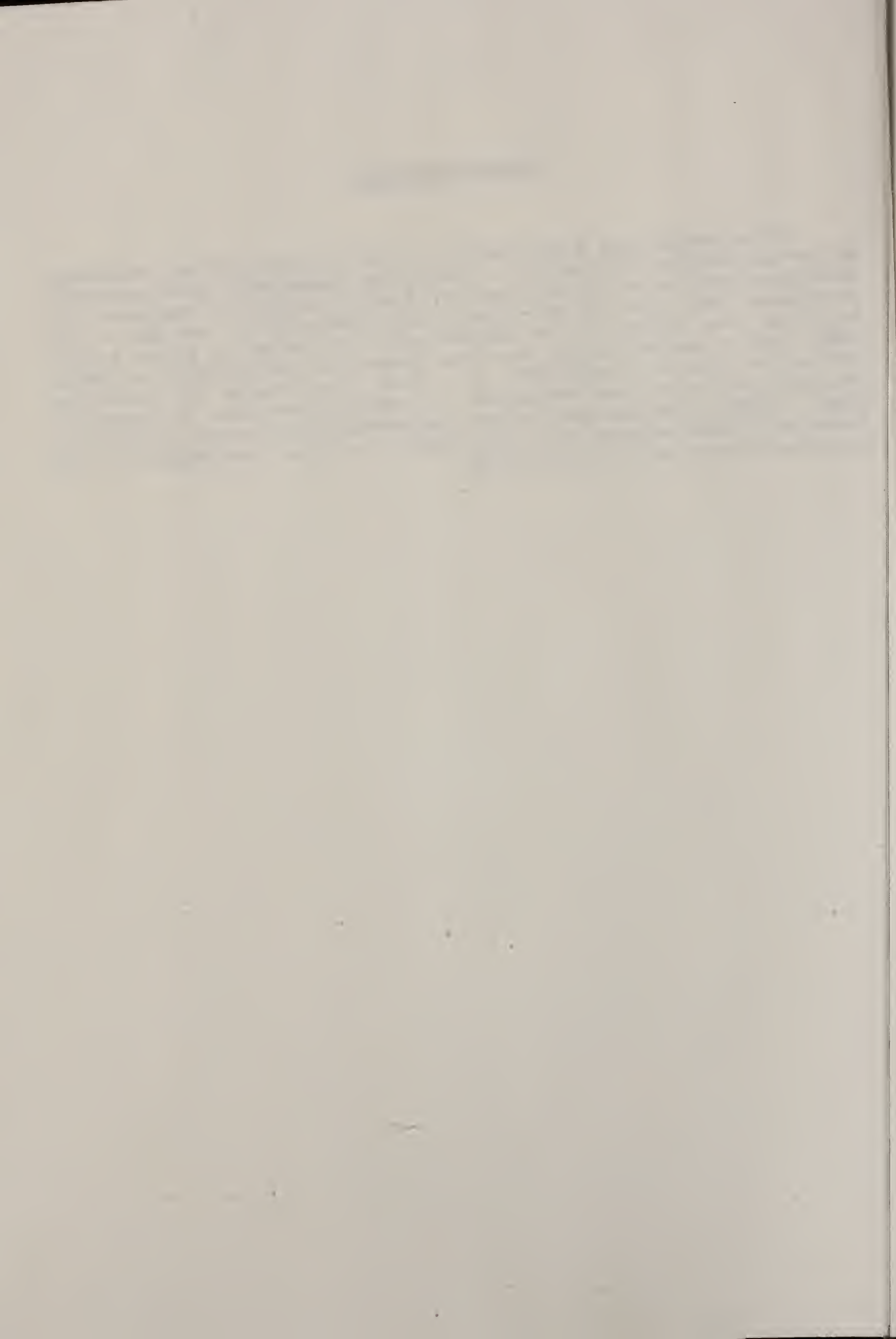


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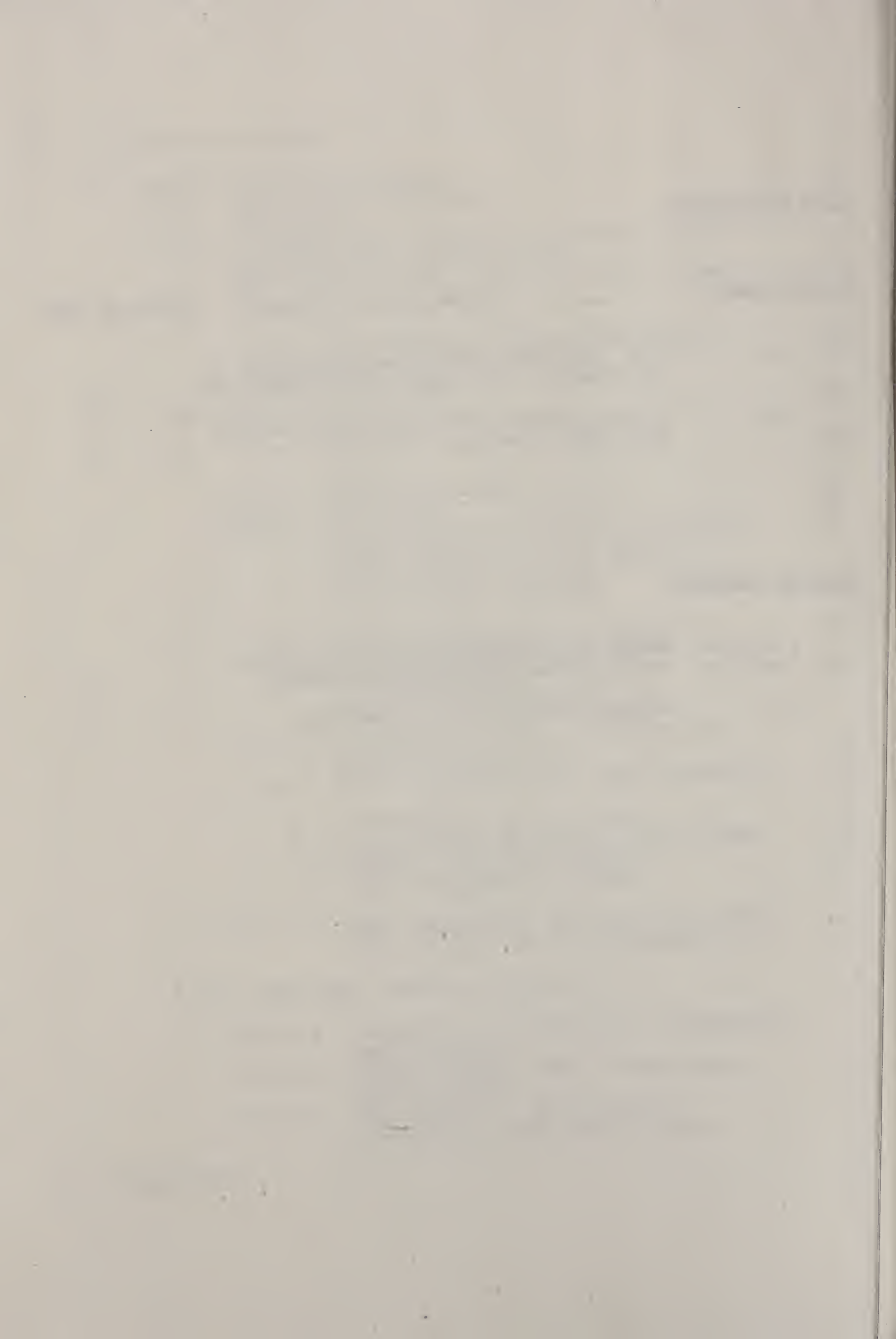
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PREFACE

This document presents the Massachusetts Department of Environmental Protection's program for evaluating risks to human health and the environment from toxic chemicals in waters of the State. It is intended to serve as a guide to the applicable regulations, guidelines and procedures dealing with this topic for various types of waters in the State. It is not intended to replace or supersede any of the statutes or regulations in place, but rather to present in one place all the relevant public health and environmental protection portions of regulations, guidelines and methodologies used by the Department for protecting this invaluable state resource.

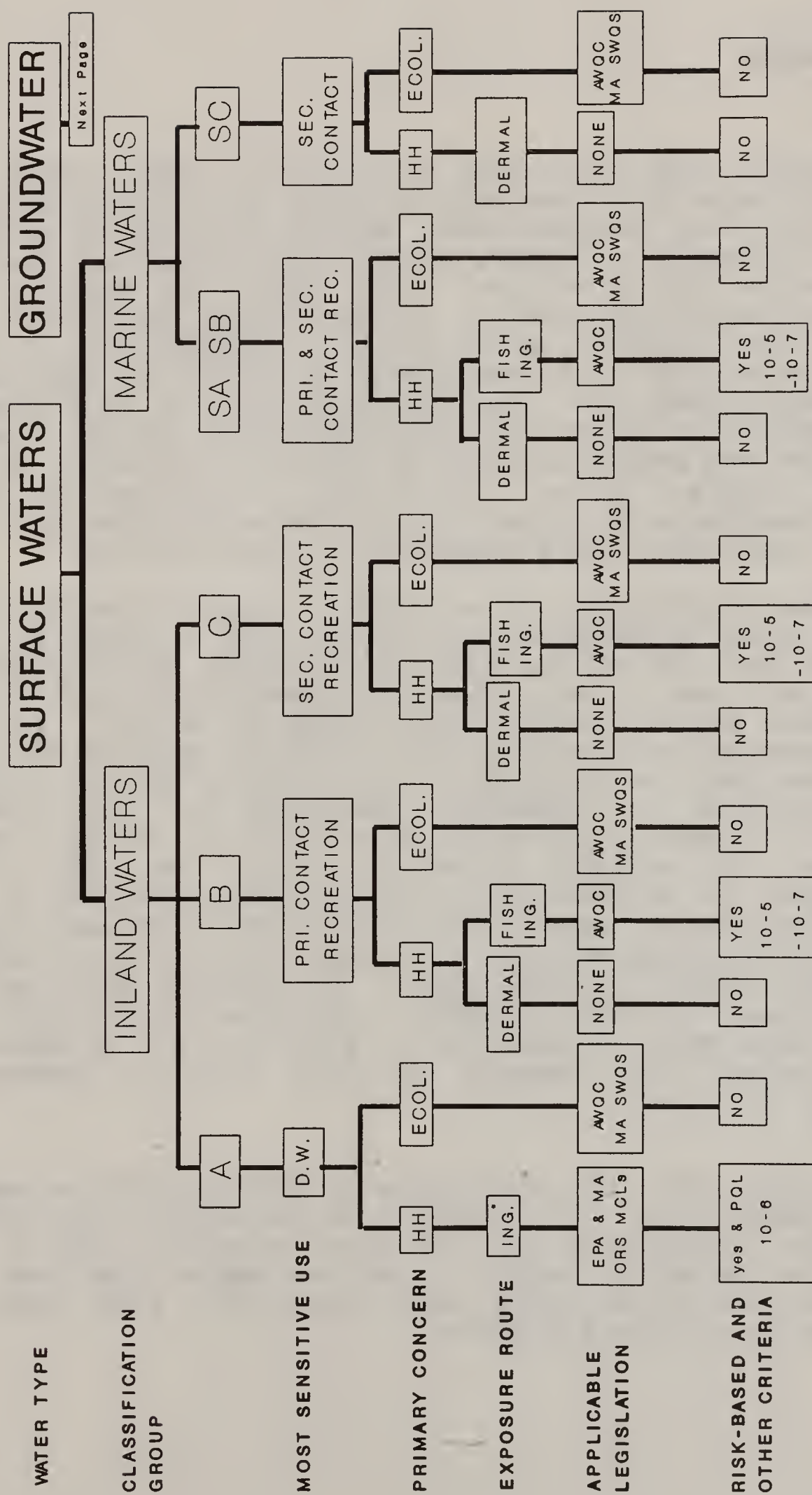
1.0 INTRODUCTION

The regulation and assessment of potential human health and environmental effects from chemicals in waters of the Commonwealth of Massachusetts are accomplished within the Department of Environmental Protection's Bureau of Resource Protection and the Office of Research and Standards. The Office of Research and Standards is primarily responsible for evaluating the health and environmental risks posed by environmental contaminants, and for providing the Bureau with risk assessments necessary for regulatory decisions. In keeping with the Bureau's goal of providing a coordinated approach to protecting the environment and citizens of the Commonwealth from potential adverse effects of chemicals in all types of water (surface water, groundwater, marine waters), this document is presented as a guide to the diverse programs that the state has for regulating toxic chemicals in state waters.

The document highlights the applicable legislation for each type of use of water or resource to be protected; it describes how standards and guidelines are derived for each case; and it presents the methodologies used to determine the hazard to humans or the environment posed by chemicals in these types of waters. In some cases, the Department has a well-developed methodology for deriving guidance or assessing health risks (e.g., drinking waters); and in others the criteria or standards developed by the federal government are the primary basis for control (e.g., protection of aquatic species in surface waters). Note that the final enforceable limits on contaminants in waters are determined by the evaluation methodologies presented in this report in conjunction with the appropriate regulations, policies, and guidelines issued by the Divisions within the Department. The federal programs are described in summary in this document. Portions of the document will serve as statements of departmental policy on how guidance is derived and hazards are assessed and will also be issued as separate policy statements.

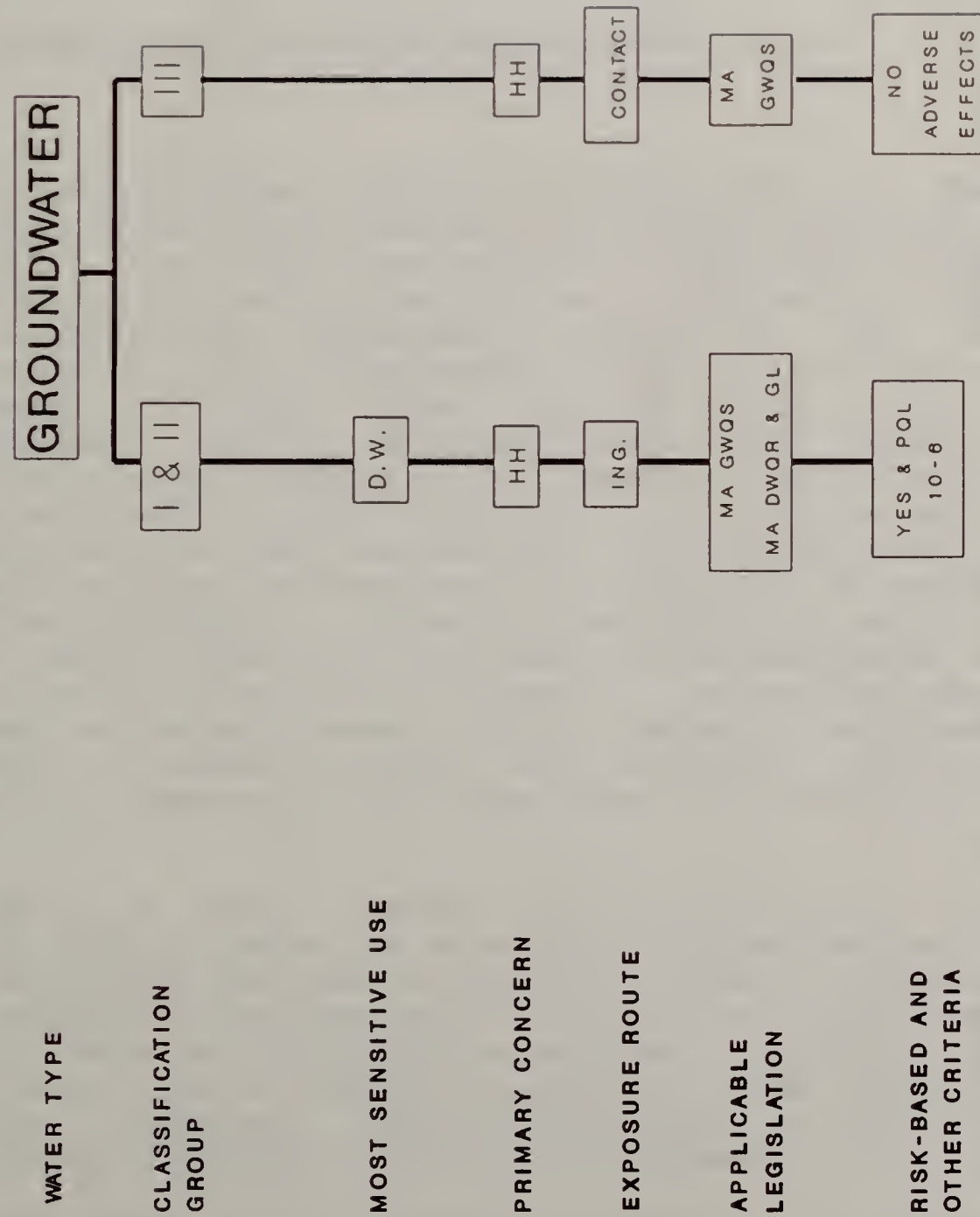
The regulatory framework applicable to Commonwealth waters is presented in Figure 1.1. The standard of protection applied to these waters is to regulate for the most sensitive use of the resource for the class of water. The two major uses are for drinking waters and non-drinking water purposes. This guide is organized along this major division.

FIGURE 1.1. REGULATORY FRAMEWORK AND PROTECTION CRITERIA
FOR MASSACHUSETTS WATERS



continued...

FIGURE 1.1. REGULATORY FRAMEWORK AND PROTECTION CRITERIA
FOR MASSACHUSETTS WATERS



ABBREVIATIONS USED:		AWQC		EPA Ambient Water Quality Criteria	
D.W.	drinking water	MA SWOS	MA SWOS	Massachusetts Surface Water Quality Standards	
HH	human health	MA ORS	MA ORS	MA DEP Office of Research and Standards	
Ecol.	ecological	Ing.	Ing.	Ingestion	
SDWA	Safe Drinking Water Act	MA GWOS	MA GWOS	MA Groundwater Quality Standards	
POL	Practical Quantitation Limit	MA DWOR & GL	MA DWOR & GL	MA Drinking Water Quality Regulations and Guidelines	
EPA HA	EPA Health Advisories				

* PRIMARY EXPOSURE ROUTE. DERMAL AND INHALATION EXPOSURES ALSO CONSIDERED IN SOME CASES.

2.0 DRINKING WATERS

There are two components to the management of toxic chemicals in drinking waters in Massachusetts. One is the use and derivation of concentrations of the chemicals in water that serve as standards or guidelines. These are individual numbers generally intended to represent concentrations of the chemicals in water which, acting alone, should pose no adverse health threat to individuals using that particular water source for their domestic water needs for a lifetime. The second component is an evaluation methodology for determining the human health risk, when chemicals are present in a water supply either singly or in combination.

2.1 APPLICABLE LEGISLATION AND REGULATIONS

Drinking water quality in the state of Massachusetts is regulated under the authority of the Safe Drinking Water Act (SDWA) of 1974. The 1986 amendments to the SDWA provide additional guidance on the regulation of toxic chemicals in drinking waters. This legislation delegates primacy to the state for the implementation and enforcement of the terms of the act. The state implements the SDWA under 310 CMR 22.0 of the Massachusetts Regulations. The U.S. EPA maintains a role in providing guidance and setting some standards for chemicals in drinking waters. The state may adopt these standards or enforce a more stringent standard of its own derivation. The first step in the federal standard-setting process is the development of Maximum Contaminant Level Goals (MCLGs). MCLGs are health goals set by EPA at levels which would result in no known or anticipated adverse health effects with a "margin of safety". Federal standards are termed Maximum Contaminant Levels (MCLs). MCLs are enforceable limits and are set as close to MCLGs as feasible. The process used to establish these numbers is described in FR 52:25690-25717, July 8, 1987.

While a modest number of chemicals are regulated at the present time and more are scheduled for regulation in coming years, many chemicals are not regulated by federal standards. The state has developed a methodology for deriving guidelines and standards for chemicals not federally regulated or for cases where the state determines that a chemical should be more stringently regulated than EPA recommends. This methodology for deriving guidance is described in Section 2.2 of this document.

The state drinking water regulations (310 CMR 22.00) provide guidance on how the individual MCLs are to be enforced for public

water supplies. The MCLs are developed to consider the health hazard posed by each single chemical acting in isolation from other chemicals that may be present in the water supply. In order to provide for the situation where mixtures of chemicals are being dealt with, the state uses a contaminated water evaluation methodology for assessing compliance with standards and for assessing human health risks posed by mixtures of chemicals (Section 2.3).

The Department of Environmental Protection's (DEP's) Division of Water Supply (DWS) uses the drinking water guidelines developed by the Office of Research and Standards (ORS) in conjunction with risk assessment information and recommendations from ORS to determine on a case by case basis the appropriate course of action at a water supply. This action may include closure, limited usage, or continued special monitoring of a water supply depending on such factors as the nature of the contamination, the magnitude of exceedance, the combination of contaminants present, and the length of exposure.

2.2 GUIDANCE DERIVATION METHODOLOGY

2.2.1 Preface

A risk assessment approach is used for deriving guidance values for individual chemicals in drinking waters. The methodology for assessing possible health effects posed by mixtures of contaminants also employs a risk assessment approach and is described in Section 2.3. Both the possible carcinogenic and other physiological non-carcinogenic human health effects of chemicals in drinking water are evaluated as part of the guidance derivation procedure for individual chemicals. The sequence of steps followed in the procedure is outlined in Figure 2.1. For all chemicals, guidance is developed to be protective of the most sensitive known adverse health effect. The basic steps in the procedure described in the following paragraphs include:

- 1) Toxicological evaluation of the chemical;
- 2) For all chemicals, determination of an allowable daily intake of the chemical protective of non-carcinogenic effects (reference dose equivalent);
- 3) For carcinogens, classification of the carcinogenic

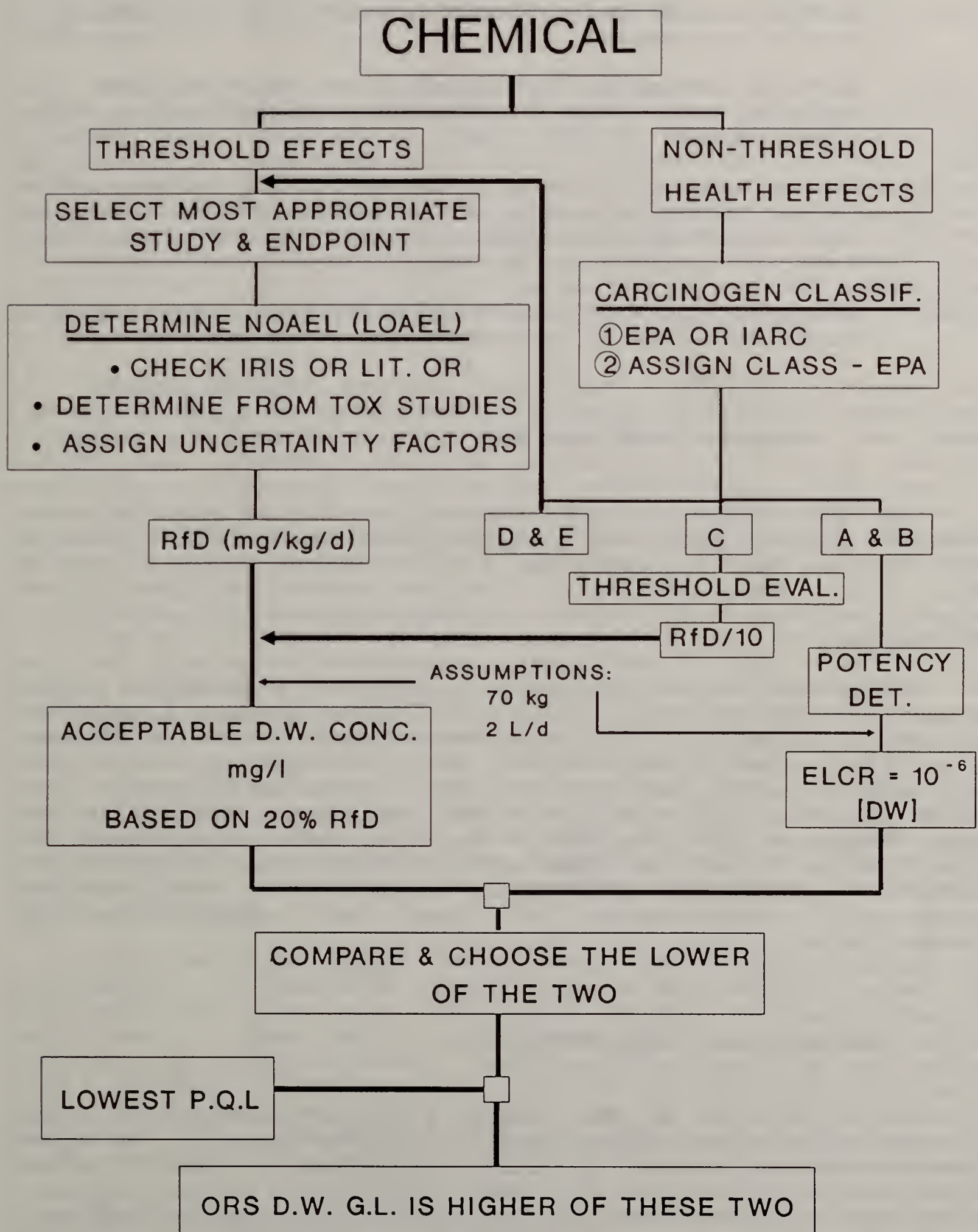


FIGURE 2.1. GUIDANCE DERIVATION METHODOLOGY

status of the chemical, and estimation of the potency of the carcinogen;

- 4) Setting estimates of exposure to the chemical via drinking water (i.e., intensity, frequency and duration of exposure);
- 5) Determination of the daily intake of the chemical which is 20% of the allowable daily intake or reference dose equivalent and/or that dose associated with a specified level of excess lifetime cancer risk;
- 6) Determination of the feasibility of applying the numerical standard derived.

2.2.2 The Risk Assessment Approach

The risk assessment methodology for developing drinking water guidance follows generally accepted procedures (EPA, 1987; NJ Drinking Water Quality Institute, 1987; Cotruvo, 1988; Wisconsin DHSS, 1988). This process involves the characterization of the potential adverse health effects of human exposures to contaminated drinking water.

A risk assessment generally consists of four major steps: hazard identification, dose-response assessment, exposure assessment, and finally, risk characterization. In the development of drinking water guidance for a particular chemical, all four steps are included, and risk management criteria are applied to derive the numerical guideline. The resultant guideline is the concentration of the chemical in drinking water which would not likely result in any adverse health effects over a lifetime's exposure. Guidelines are health based, while standards may incorporate consideration of cost and feasibility of implementation.

2.2.3 Toxicological Characterization

The first step of the procedure is to identify the toxic effects that have been associated with a given chemical. Two major types of toxic effects are generally recognized: threshold (often called non-cancer) and non-threshold (often called cancer) effects. Virtually all chemicals exhibit threshold effects, while relatively few have been shown to exhibit non-threshold effects. This step corresponds to the hazard identification phase of the risk assessment procedure and is the process for determining what

adverse health effects might be associated with exposure to a given substance.

Four general classes of information may be used in this step: human epidemiological data and clinical case studies, animal bioassay data, data on in vitro effects of the chemical, and comparisons of molecular structure. Studies used in setting ORS drinking water guidelines are chosen to represent, as closely as possible, long-term human exposure to contaminated drinking water. Sound human data are therefore preferred. When human data are not available, studies in which animals were exposed via the oral route are preferred to those in which animals were exposed via inhalation or other exposure routes. Long-term exposures are preferred over shorter-term and acute exposures.

Epidemiological studies that show a positive association between exposure to a chemical (preferably in drinking water) and a disease are accepted as the most convincing evidence for human health risk. However, very few epidemiological studies provide conclusive evidence of a cause/effect relationship. Also, most of the chemicals in the environment have not been studied with epidemiologic methods. These limitations necessitate a reliance on less direct evidence that a health hazard may be related to a chemical exposure.

The most commonly available and relied upon data are those obtained from animal bioassays. The inference that results from animal experiments are applicable to humans is fundamental to toxicologic research. Summaries of animal bioassay studies are found in U.S. EPA Health Assessment documents, health advisories, and on the Integrated Risk Information System (IRIS) - a computerized data base maintained by the U.S. Environmental Protection Agency. The National Toxicology Program (NTP) publications, and the Agency for Toxic Substances and Disease Registry (ATSDR) publications are further sources of information. Preferred data come from chronic exposure studies, preferably ingestion studies.

Short-term in vitro tests serve as another source of information. A positive response in a mutagenicity assay is supportive evidence that the agent tested is likely to be carcinogenic. Such data, in the absence of a positive animal bioassay, are rarely, if ever, sufficient to support a conclusion that a chemical is carcinogenic. But because short-term tests are rapid and inexpensive, they are valuable for screening chemicals for potential carcinogenicity and for lending additional support to observations from animal and epidemiologic investigations.

The final source of hazard information used when epidemiologic and animal studies are insufficient or lacking, is the comparison of a chemical's structure and activity with those of known carcinogens or other toxins. Structure and activity comparisons,

however, are used only as a last resort. This is because chemicals are unique and experimental data support such associations for only a few structural classes.

With knowledge of its toxicological characteristics, the non-cancer and cancer effects of a chemical are evaluated. In both cases, a dose-response assessment is performed. This step corresponds to the second step of the risk-assessment procedure. Here, the relationship between a dose of a chemical and the incidence of an adverse health effect is identified. From this point, an allowable daily intake or reference dose equivalent for non-carcinogenic effects and a potency factor for carcinogenic potential are derived, or adopted from IRIS.

2.2.4 Reference Dose (RfD) Equivalent Derivation for Non-Carcinogenic Health Effects

Non-carcinogenic effects are those which are believed to occur only above some threshold dose. An RfD equivalent is derived if an RfD is not available from IRIS. The RfD or RfD equivalent is an estimate of a sub-threshold human dose. Doses that are less than or equal to the reference dose are not likely to be associated with any adverse health effects. The RfD is an estimate of the daily dose of a chemical that a human may be exposed to without incurring any appreciable risk of an adverse health effect during their lifetime.

The first step in the derivation of an RfD or RfD equivalent is the identification of a No Observed Adverse Effect Level (NOAEL), or in the absence of a NOAEL, a Lowest Observed Adverse Effect Level (LOAEL). Ideally, a NOAEL should be identified in the most sensitive test population, and should reflect a dose at and below which no adverse effects are likely after chronic oral exposures. If several species are tested, the most sensitive species is that which exhibits adverse health effects at the lowest doses (i.e. has the lowest NOAEL). If several studies are performed on the species identified as the most sensitive, the highest NOAEL is chosen for derivation of the RfD. If a chronic oral NOAEL cannot be identified from the toxicological literature, a chronic LOAEL may be used. If chronic oral exposure studies are unavailable, then subchronic studies are the next choice. The human RfD or equivalent is estimated by extrapolating the results of animal studies to the human condition.

The RfD is derived by dividing the NOAEL (or LOAEL if a suitable NOAEL is not available) for subchronic or chronic exposure by one or more uncertainty factors (UF) times a modifying factor (MF):

$$\text{RfD} = \frac{\text{NOAEL or LOAEL}}{\text{UF} \times \text{MF}}$$

The uncertainty factor used in calculating the RfD reflects scientific judgement regarding the various types of data used to estimate RfD values. An uncertainty factor of 10 is usually used to account for variation in sensitivity within the human population. An additional 10-fold factor is used for each of the following extrapolations: from long-term animal studies to the case of humans; from a LOAEL to a NOAEL; and from a subchronic study to a chronic study. In order to reflect professional assessment of the uncertainties of the study and database not explicitly addressed by the above uncertainty factors (e.g. completeness of the overall database), an additional modifying factor ranging from 1 to 10 is applied (U.S. EPA, 1989. Health Effects Assessment Summary Tables.)

2.2.5 Potency Determination for Carcinogens

2.2.5.1 Carcinogen Classification Procedure. Carcinogens are classified on the basis of the strength and type of evidence for carcinogenicity. The categorization scheme used places chemicals into five groups, A - E (U.S. EPA, 1986) as shown in Table 2.1. These groups are then reassigned to one of three categories where drinking water is being addressed (U.S. EPA, 1985).

Category I includes Groups A and B, i.e., those chemicals which are known or probable human carcinogens with strong evidence of carcinogenicity. Category II includes Group C, those chemicals with equivocal evidence of carcinogenicity. Category III includes Groups D and E, which are generally considered noncarcinogens because of either no, nonpositive or inadequate evidence of carcinogenicity. Those chemicals in Category II with equivocal evidence of carcinogenicity are treated as noncarcinogens (using procedure described in Section 2.2.4) with an additional uncertainty factor of 10 applied to account for their unclear carcinogenic status. In most cases, Category III chemicals can only be evaluated for noncarcinogenic effects.

2.2.5.2 Carcinogen Potency Determination. Carcinogenesis is assumed to have no threshold; i.e., exposure to any concentration of a carcinogen is assumed to be associated with some finite probability of tumor formation. The potency of the chemical is determined from the dose-response data. The potency is the cancer risk associated with a dose of 1 mg/kg/day, or in more general terms, the risk per unit dose (slope of the dose response curve).

TABLE 2.1 U.S. EPA CATEGORIZATION OF WEIGHT OF EVIDENCE
FOR HUMAN CARCINOGENICITY

GROUP	CLASS	DESCRIPTION
A	Human Carcinogen	Sufficient evidence from human epidemiological studies.
B	Probable Human Carcinogen.	GROUP B1: Limited evidence from human epidemiological studies. GROUP B2: Sufficient evidence from animal studies and inadequate or no data from human epidemiological studies.
C	Possible Human Carcinogen	Limited evidence of carcinogenicity from animal studies in the absence of human data.
D	Not Classifiable As To Human Carcinogenicity	Inadequate human and animal evidence carcinogenicity or no data available.
E	Evidence of Non-carcinogenicity for humans	No evidence for carcinogenicity in at least two adequate animal tests or in both adequate human epidemiological and animal studies.

* Source: FR51:33992-34003. September 24, 1986.

Quantitative carcinogenic risk assessments are performed for chemicals in Category I (Groups A and B), and on a case-by-case basis for chemicals in Group C. Cancer risk and potency factors are estimated through the use of mathematical extrapolation models, most commonly the linearized multistage model, for estimating the largest possible linear slope (within the 95% confidence limit) at low extrapolated doses that is consistent with the data. The cancer potency or risk is characterized as an upper-bound estimate: i.e., the true risk to humans, while not identifiable, is not likely to exceed the upper-bound estimate, and may in fact be lower. The units of oral potency factors are usually in the form of risk per mg/kg/day of the chemical or $(\text{mg/kg/day})^{-1}$.

2.2.6 Derivation of Drinking Water Guidance Concentrations

The human reference doses or cancer potencies determined above are next used to identify allowable concentrations of contaminants in drinking water. Allowable concentrations yield a dose no greater than 20% of the oral reference dose and a dose associated with a lifetime cancer risk equal to one in one million respectively. Dose-response information is used with drinking water exposure information to derive the allowable concentrations. The process of measuring or estimating the intensity, frequency, and duration of human exposure to a chemical through drinking water ingestion is the third step of the risk assessment process: exposure assessment. The standard assumptions used by U.S. EPA and by ORS are:

Lifetime average bodyweight: 70 kg
 Lifetime average ingestion rate: 2 liters drinking water/day
 Relative source contribution from drinking water: 20%

The relative source contribution factor of 0.2 comes from the assumption that only 20% of the daily exposure to compounds comes from water and that the remaining 80% of exposure would result from other sources such as air or food (U.S.EPA, 1985).

The health based guidance level protective of non-carcinogenic effects is calculated as follows:

$$\text{mg/L in water} = \frac{\text{oral RfD (mg/kg/day)} \times 70 \text{ kg} \times 0.2}{2 \text{ L/day}}$$

The drinking water guidance considered protective of carcinogenic health effects is chosen to be that concentration of a compound associated with an excess lifetime cancer risk of one in one million (1×10^{-6}). One in one million represents an extremely small additional lifetime cancer risk, and an increased incidence of this magnitude is not measurable in a population by epidemiological techniques (N.J. Drinking Water Quality Institute, 1987). This risk level is insignificant when compared with the estimate that about 76 million Americans now living will eventually have cancer; or about three in ten according to present rates (American Cancer Society, 1989). Therefore, an estimated increased lifetime cancer risk of one in one million is regarded as an acceptable and insignificant additional risk from a single contaminant.

To derive the risk specific concentration of a carcinogen in drinking water, the specified level of risk is multiplied by 70 kg and divided by the oral potency factor and by 2 L/day:

$$\text{mg/L in water} = \frac{1 \times 10^{-6} \times 70\text{kg}}{\text{oral P.F. (mg/kg/day)}^{-1} \times 2 \text{ L/day}}$$

The derivation of the health-based guidance is in essence the risk characterization step of a risk assessment. The guidance value is that concentration of a chemical that is not anticipated to be associated with any adverse health consequences in exposed populations.

Drinking water guidance for individual chemicals is based primarily on the health effects posed by ingestion. Use of drinking water for purposes other than drinking, especially bathing, may also allow contaminants to enter the body through inhalation and/or skin absorption. Future guidance values may include an evaluation of these routes of exposure. Current guidelines are set at values believed to be protective of other routes of exposure. On a chemical-specific basis, other routes of exposure are examined if there is reason to believe that ingestion is not the primary route of toxicity.

2.2.7 Final Determination of Appropriate Guidance Concentrations

Health-based guidelines are the lower of two possible concentrations: 1) the concentration which could be associated with

cancer risks (due to lifetime ingestion of contaminated water) of no more than one in one million, or 2) the concentration which is associated with twenty percent of the reference dose for non-carcinogenic effects. ORS guidelines for noncarcinogens are set at concentrations which shall eliminate within the limits of practicability and feasibility, all adverse physiological effects which may result from ingestion of contaminated water. ORS uses twenty percent of the non-carcinogen oral reference dose to develop this guidance.

If the lower of these two concentrations is not a feasible level for detection purposes, and therefore impractical from an enforcement viewpoint, the ORS guideline is then based on the practical quantitation level (PQL). PQLs are defined as the lowest levels that can be reliably achieved within specified limits of precision and accuracy of the analytical results during routine laboratory conditions (FR 54 No 97 May 22, 1989). These limits are plus or minus 40% of true value for concentrations less than 0.010 mg/L and plus or minus 20% of true value for concentrations greater than 0.010 mg/L. In all cases addressed so far, guidance values for chemicals without evidence of carcinogenicity are entirely health-based, i.e. the PQLs for these compounds are below the non-carcinogenic health-based guideline. For some carcinogens, however, final guidance has been set at the PQL. In these cases, the 10^{-6} risk-based concentration is below the PQL for that compound. Every effort is made to ensure that the ORS guidelines for carcinogens are set as low as practicably feasible.

The nominal residual cancer risks that are theoretically associated with exposures at the PQLs are examined, and a decision is made whether they are acceptable from a safety standpoint. Exceptions to these decision criteria include those carcinogenic compounds with public health benefits (e.g., disinfecting agents), or where natural concentrations of the chemical are above the health based guidelines and widespread treatment is impractical. In some instances, a risk-benefit analysis is performed.

2.3 CONTAMINATED DRINKING WATER EVALUATION

2.3.1 Applicable Situations

Several approaches are used in DEP to evaluate the potential health hazard posed by toxic chemicals in drinking waters. These approaches are dependent upon the availability of standards or guidelines for comparison. The alternatives are discussed in each of the following subsections.

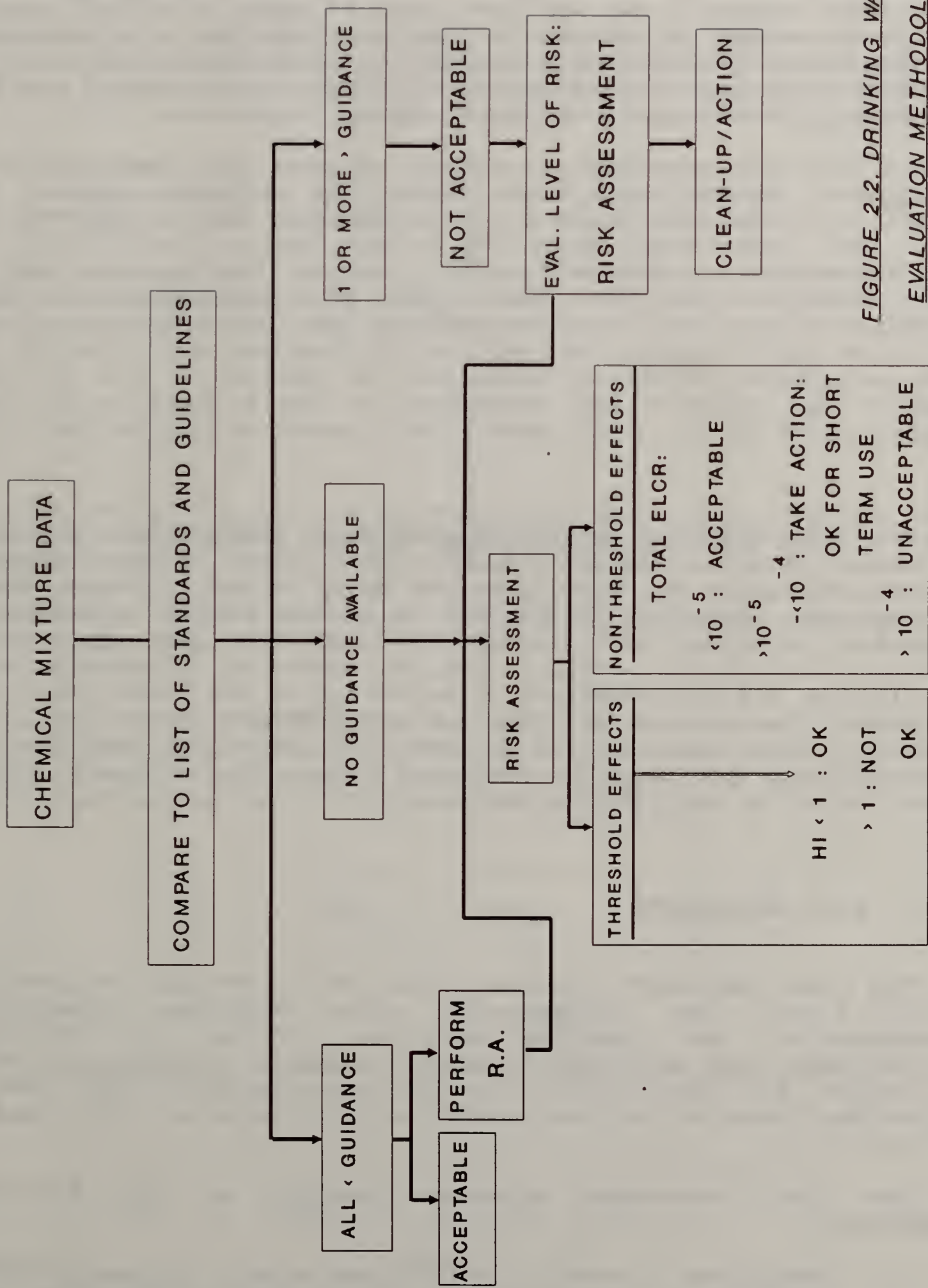
The decision alternatives recognize that the basis for control of drinking water quality is the federal system of MCLs for individual chemicals. These numbers are derived to be protective of public health on an individual chemical basis and incorporate some consideration of feasibility of implementation and cost. When the situation arises where standards or guidelines are not available for all chemicals in a water supply, then a risk assessment approach is used for the evaluation of mixtures of chemicals. In some cases, even when standards or guidelines are available for the chemicals present in the mixture, a risk assessment is performed.

2.3.2 Decision Alternatives

The decision process for evaluating health hazards from toxic chemicals in drinking waters is presented in Figure 2.2. The process involves comparing the chemical composition data for the water supply to a list of standards and guidelines for the state. The possible outcomes of this comparison along with actions taken are illustrated in Figure 2.2.

2.3.2.1 All Chemicals With Standards or Guidelines. In cases where guidance (standard or guideline) is available for all chemicals in a drinking water source, the concentration of each chemical is compared to the respective guidance level for that chemical. Exceedances of MCLs are identified according to the guidance contained in 310 CMR 22.06, 22.07, and 22.09.

In cases where all chemical concentrations are less than the guidance, a water system may be judged to pose no unacceptable human health hazard. However, the characteristics of the chemicals occurring together are considered: the toxicological nature of each compound; its concentration in the water; and its proximity to the guidance value. In cases with mixtures where all or most chemical concentrations are slightly below the guidance concentrations, or



**FIGURE 2.2. DRINKING WATER
EVALUATION METHODOLOGY**

some chemicals are of particular concern, then it is recognized that these chemicals may act in concert to exert an effect greater than that exerted by any one of them individually. In this case, a risk assessment (Section 2.3.3) may be performed to quantify the potential carcinogenic and non-carcinogenic health hazard posed by the mixture of chemicals acting together.

If the concentrations of one or more of the chemicals in a supply are greater than their respective guidance values, the situation may be sufficient to deem the water source unacceptable (i.e., MCL exceedance) according to 310 CMR 22.06 and 22.07. A risk assessment is then performed to assess the type and level of risk posed by the chemicals. The risk assessment provides information that can then be used as the basis for management decisions about appropriate action or clean-up according to the risk management criteria presented in Section 2.3.7. of this document and policies and procedures of DEP's Division of Water Supply.

2.3.2.2 Some Chemicals Without Standards or Guidelines. When this situation exists, it is possible for some of the chemical concentrations to exceed MCLs and to have the water source deemed unacceptable according to 310 CMR 22.06 and 22.07. However, in order to provide risk management guidance and incorporate consideration of the potential health effects of all chemicals in the mixture, a risk assessment is performed on the chemicals in the mixture. The assessment addresses both threshold-type and non-threshold-type effects. Risk management criteria described in Section 2.3.7 are used to evaluate the degree of human health hazard posed by the chemical mixture.

2.3.3 Risk Assessment

The risk assessment approach used for evaluating the possible health risks from contaminated water supplies takes into consideration the possible additive effects from multiple contaminants and multiple exposure routes (ingestion, dermal absorption, and inhalation.) The risk management criteria used to decide what remedial actions should be considered are described in Section 2.3.7.

The risk assessment process consists of the following components:

- i. comparing ingested, inhaled and dermal intakes (Average Daily Dose) of individual contaminants to Reference Doses (which represent allowable daily intakes considering only

threshold effects);

- ii. estimating the likelihood of threshold effects due to the combined effects of ingestion, inhalation and dermal absorption for all the contaminants in a supply or well. This assessment is made using a Hazard Index approach;
- iii. estimating total excess lifetime cancer risks corresponding to ingested, inhaled and dermal intake for each of the contaminants in a supply or well;
- iv. estimating total excess lifetime cancer risks corresponding to ingestion, inhalation and dermal absorption for all the contaminants in a supply or well.

2.3.4 Estimation of Average Daily Dose (ADD) for Drinking Water

The estimation of the average daily dose of a chemical that an individual receives through ingestion of water, inhalation and dermal absorption is one component of the assessment of the health hazard of a chemical. This number may then be compared with a concentration deemed to be acceptable for lifetime exposure to estimate the relative likelihood of the occurrence of adverse health effects.

An individual's Average Daily Dose from a source of drinking water is the sum of the ADDs for ingestion of the drinking water (ADD_{dwi}), dermal contact with the water (ADD_{dwd}), and inhalation of volatilized contaminants from that water (ADD_{dwih}):

$$ADD_{dw} = ADD_{dwi} + ADD_{dwd} + ADD_{dwih}$$

where:

ADD_{dwi} : ADD from Ingestion of Contaminated Drinking Water:

$$ADD_{dwi} = \frac{[Cont]_{dw} * VI * BAF * D_2 * C}{BW_{avg} * AP}$$

where:

[Cont] _{dw}	=	Representative concentration of contaminant in the drinking water (dimensions: mass/volume)
VI	=	Daily volume of drinking water ingested (dimensions: volume/time)
BAF	=	Bioavailability Adjustment Factor
D ₂	=	Duration of the exposure period (dimension: time)
BW _{avg}	=	Average body weight of the receptor of concern during the averaging period (dimension: mass)
AP	=	Averaging Period (dimension: time)
C	=	Appropriate units conversion factor(s).

ADD_{dwd}: ADD from Dermal Contact with Contaminated Drinking Water:

$$ADD_{dwd} = \frac{[Cont]_{dw} * SA * PC * BAF * F * D_1 * D_2 * C}{BW_{avg} * AP}$$

where:

[Cont] _{dw}	=	Representative concentration of contaminant(s) in the drinking water (dimensions: mass/volume)
SA	=	Skin surface area in contact with the surface water during the period of exposure. (dimension: area)
PC	=	Permeability Constant (dimensions: volume/time*area)
BAF	=	Bioavailability Adjustment Factor
F	=	Number of exposure events during the exposure period divided by the number of days in the exposure period (dimensions: events/time)

- D_1 = Average duration of each exposure event (dimensions: time/event)
 D_2 = Duration of the exposure period (dimension: time)
 BW_{avg} = Average body weight of the receptor of concern during the averaging period (dimension: mass)
 AP = Averaging Period (dimension: time)
 C = appropriate units conversion factor(s)

ADD_{dwh}: ADD for Inhalation of Contaminants from Drinking Water

$$ADD_{dwh} = \frac{[cont]_{air} * VR * BAF * D_1 * D_2 * F * C}{BW_{avg} * AP}$$

Where:

- $[Cont]_{air}$ = Representative concentration of gaseous chemical contaminant in the air during the period of exposure (dimensions: mass/volume)
 VR = Daily respiratory volume for the receptor of concern during the period of exposure. (dimensions: volume/time)
 BAF = Bioavailability Adjustment Factor
 F = Number of exposure events during the exposure period divided by the number of days in the exposure period (dimensions: events/time)
 D_1 = Average duration of each exposure event (dimensions: time/event)
 D_2 = Duration of the exposure period (dimension: time)

BW_{avg}	=	Average body weight of the receptor of concern during the averaging period (dimension: mass)
AP	=	Averaging Period (dimension: time)
C	=	Appropriate units conversion factor(s)

Dermal absorption and inhalation of chemical contaminants may occur while an individual is in contact with the drinking water. Typically these exposures would take place during showering, bathing, washing dishes, cooking and other household activities. The Average Daily Dose received via inhalation exposures and dermal absorption from drinking water during household activities (ADD_{dwh} and ADD_{dwd}) may be calculated using the equations presented. If information sufficient for calculating ADD_{dwd} and ADD_{dwh} are not available, default exposure assumptions as described in Section 2.3.5 may be used.

2.3.5 The Hazard Index: Assessing Potential for Non-Cancer Effects.

In order to assess the degree of potential health threat posed by the calculated average daily dose (ADD) for each chemical in the mixture, each ADD is divided by the respective RfD or RfD equivalent for each chemical. These individual hazard indices (HI) can then be summed to provide an estimate of the likelihood of threshold-type health effects for the mixture of chemicals.

The hazard index is an additive model recommended for systemic toxicants (U.S EPA, 1986). Several studies have demonstrated that dose additive models often predict reasonably well the toxicities of mixtures composed of a substantial variety of both similar and dissimilar compounds (EPA FR 51:34013-34025, 1986). Dose addition is not the most biologically plausible approach if the compounds do not have the same mode of toxicologic action. Therefore, the assumption of dose addition is most properly applied to compounds that induce the same effect by similar modes of action.

A separate hazard index should be generated for each end-point of concern and for each exposure route of concern (ingestion, inhalation, and dermal absorption). Therefore, as an example, the Ingestion Hazard Index for a mixture of contaminants with the same mechanism of toxic action is calculated as follows:

$$\text{Ingestion HI} = \sum_{i=1}^{i=n} \frac{\text{ADD}_i}{(\text{RfD}_i)}$$

where:

ADD_i = the average daily dose from ingestion for the i^{th} chemical in the mixture;

RfD_i = EPA verified Reference Dose in mg/kg/day for the i^{th} chemical in the mixture;

In order to account for the exposures to volatile organic compounds via dermal absorption and inhalation, the Average Daily Dose received via dermal absorption (ADD_{dwd}) and via inhalation (ADD_{dwh}) are calculated as noted in Section 2.3.4.

The hazard index provides a rough measure of the likely toxicity and requires cautious interpretation. Generally, as the hazard index approaches unity, concern for the potential hazard of the mixture increases. For this reason a risk management decision has been made which places the acceptable non-carcinogenic hazard index limit at 1.

The hazard indices calculated for each exposure route and for each group of similar compounds are compared to the total non-carcinogenic risk limit of 1.

Currently, there are no dermal reference doses or reference dose equivalents. There are a few inhalation reference doses published in EPA's Health Effects Assessment Summary Tables. When an EPA verified inhalation reference dose is not available, a DEP Allowable Threshold Concentration (ATC) may be used for air exposures. The ATC values are adjusted Threshold Effects Exposure Limits (TELEs) as presented in Chemical Health Effects Assessment Methodology and Method to Derive Allowable Ambient Limits (MA DEP, 1990). The Allowable Threshold Concentrations may be used to derive reference dose equivalents in the following manner:

$$\text{RfD-equivalent (inh)} = \text{ATC} * 10 \text{ m}^3/\text{day} * 1/20 \text{ kg} * C$$

Where:

ATC = The Allowable Threshold Concentration

$10 \text{ m}^3/\text{day}$ = Average Child Ventilation Rate

1/20 kg = Inverse of the Average Child Body Weight

C = Units Conversion Factor

In situations where there is not sufficient information to calculate dermal and inhalation doses of chemical contaminants associated with household use of drinking water, some assumptions can be made about the contribution of these two exposure routes.

In general, unless there is evidence which indicates otherwise, exposures via inhalation are important only for volatile organic compounds. Inhalation exposures to nonvolatile organic and inorganic substances during household use of drinking water may be assumed to be zero.

Shehata (1985), U.S. EPA Office of Toxic Substances (1985), and Andelman (1985) indicate that, at least for some volatile organic compounds, the magnitude of the inhalation exposures related to non-ingestion uses of contaminated water is at least equal to the magnitude of the exposures associated with drinking that water (adult 2 liters/day, child 1 liter/day).

It has also been suggested that the magnitude of exposure via dermal absorption to certain VOCs during showering and bathing may be equivalent to the magnitude of exposures associated with drinking that water (adults: 2 liters/day, children: 1 liter/day) (Brown et al., 1984). Another study of the dermal absorption rates of 53 chemicals showed that dermal absorption was estimated to account for, at most, 25 percent of the exposure expected from ingestion of 2 liters of drinking water daily (Vanderslice n.d.)

When there is insufficient information for direct calculation of doses of VOCs in drinking water via inhalation and dermal absorption, it may be assumed that the doses via ingestion, inhalation and dermal absorption are equivalent. This assumption may be incorporated into the equation for estimating the total Hazard Index.

When inhalation and dermal RfDs or RfD-equivalents are unavailable, the total HI (ingestion, inhalation and dermal absorption) may then be estimated by three times the Ingestion Hazard Index:

$\text{Total HI} = (3) \times (\text{Ingestion Hazard Index})$
--

2.3.6 Non-Threshold Effects Evaluation

The risks associated with non-threshold health effects (i.e., carcinogenesis) are characterized by focusing on estimated Excess Lifetime Cancer Risk (ELCR) for the theoretical individual who spends his/her lifetime exposed to the contaminated drinking water. For an individual contaminant and for the ingestion route of exposure, the ELCR is calculated as shown below. The total cancer risk is calculated by summing the estimated excess lifetime cancer risks associated with the theoretical individual's exposure, over the next 70 years, to each of the contaminants present in the drinking water. This approach includes the estimated lifetime cancer risks posed by each exposure route. The ELCR is the probability that an individual would develop cancer as a result of exposure to a given chemical.

$$\text{ELCR}_{\text{ingestion}} = (\text{LADD}_{\text{ing}})(\text{Potency Value})$$

where:

LADD_{ing} = Lifetime average daily dose received via ingestion of drinking water (mg/kg/day).

Potency = the upper 95% confidence limit on the cancer slope value (mg/kg/day)⁻¹.

If information is not sufficient to estimate the cancer risks posed via the inhalation and dermal exposure routes (i.e. cannot estimate ADD_{dwh} and ADD_{dwd} , and there are no inhalation and dermal absorption potency factors for the contaminants in question), and it is assumed that the total dose via ingestion, inhalation, and dermal absorption is equal to three times the ingested dose, then the estimated ELCR due to ingestion, inhalation and dermal absorption of water containing a given chemical is assumed to be three times the ELCR due to ingestion alone. Note that this is a default exposure assumption, and that this factor may change as better information becomes available.

$$\text{ELCR}_i = (3) \times \text{ELCR}_{i,\text{ingestion}}$$

where:

ELCR_i = the excess lifetime cancer risk associated with ingestion, inhalation and dermal absorption of chemical i;
 ELCR_{i, ingestion} = the excess lifetime cancer risk associated with ingestion of chemical i.

In the case where a mixture of contaminants is present, the ELCR due to ingestion, inhalation and dermal absorption of all the chemicals present would equal the sum of the ELCRs (ELCR_i) for each of the chemicals. For the evaluation of cancer risk for water supplies, the assumption is made that exposed individuals will be exposed to the same concentrations throughout their 70 year lifetimes.

2.3.7 Risk Management Criteria for Mixtures of Chemicals in Drinking Water Supplies

2.3.7.1 Threshold Effects. A Total Hazard Index greater than 1.0 indicates the possibility of threshold effects resulting from longer term exposure to contaminated drinking water. A Total Hazard Index less than or equal to 1.0 indicates that threshold (non-carcinogenic) effects would not be expected to occur as a result of exposure to the contaminated drinking water for any period of time.

2.3.7.2 Non-Threshold Effects. ORS and DWS consider a total ELCR greater than 1 in 10,000 (1×10^{-4}) an unacceptable risk. If, based on reported levels of contamination and an assumed lifetime exposure to the contaminated source, the total ELCR is greater than 1 in 10,000, immediate closure of the well is recommended.

A total ELCR greater than 1 in 100,000 yet less than 1 in 10,000 ($1 \times 10^{-5} < \text{ELCR} < 1 \times 10^{-4}$) is considered an unacceptable risk for long term exposure. Under certain conditions, limited short term use of the well or source may be allowed pending remedial action. Continued special monitoring of the source during this compliance period is recommended.

A total ELCR less than 1 in 100,000 (1×10^{-5}) is considered acceptable for long term use of the source, although regular monitoring should continue to ensure that contaminant concentrations remain low.

The excess lifetime cancer risk of one in one hundred thousand

used as the "acceptable" limit when evaluating mixtures of contaminants in a water supply differs from the target risk level of one in one million used to derive guidelines for individual chemicals (as described in Section 2.2.6). Although this may seem inconsistent, guidelines for individual chemicals are targeted at a lower risk limit than the acceptable risk limit for mixtures of contaminants for the following reason. Drinking water guidelines may often be used by those outside ORS in lieu of a risk assessment when more than one chemical is present in a water supply. The situation could occur where a mixture of chemicals was present, each at or below its respective guidance concentration, and the total ELCR for the mixture could be sufficiently high to be of concern. In order to minimize the possibility of this happening, the individual target risk is set an order of magnitude below that for a mixture of chemicals. There will be some instances where a few chemicals may be present together at concentrations greater than their respective guidance levels and hence be at unacceptable concentrations when judged by that criterion; yet the total ELCR posed by the mixture is judged acceptable (i.e. less than or equal to 1×10^{-5} ELCR) when evaluated against the mixture risk criterion. Management decisions in these cases will be made by DWS and ORS.

2.4 LIMITATIONS AND UNCERTAINTIES

The procedures described above represent the most current approaches to guideline derivation and evaluation of hazards posed by chemicals in potable waters. Nevertheless, there are several shortcomings in the methodologies which should be noted.

The relative source contribution factor in guidance derivation has standardly been used to account for other non-drinking water exposures to chemicals. In theory, this approach is valid, but in practice it is constrained by the nature of toxicological data generated in support of chemical hazard assessment. Adjustment of an exposure route-specific ingestion RfD to reflect exposures that may come from other exposure routes such as inhalation or dermal is constrained by the fact that the body's capacity for detoxifying, sequestering or eliminating chemicals may differ between routes of entry into the body. Route-specific RfDs reflect the body's capacity to handle chemicals introduced to it through that particular exposure route. There are no good estimates of the body's overall capacity for chemical resistance through simultaneous multiple routes of exposure ($\text{RfD}_{\text{whole body}}$). The complexity of multiple route dosing has precluded generation of whole animal RfDs representing the systemic capacity to deal with chemical exposure.

The adjustment that is therefore made for relative source contribution in drinking water uses 20% as a lower default value and other chemical-specific values when available.

Guidance and hazard evaluations are based upon lifetime exposures. Frequently the hazards from less than lifetime exposures are of interest and methods for assessing risks associated with these exposures have some limitations. Evaluation of non-carcinogenic effects for less than lifetime exposures is possible because acceptable doses are based upon daily intake. However, exposure to carcinogens is evaluated over an entire lifetime. The understanding of the toxicological nature of tumor formation in relation to shorter-term exposures is incomplete and therefore it is not possible to quantitatively evaluate less than lifetime cancer risks with any degree of certainty. In cases where cancer risks from a contaminated water supply are judged to be acceptable ($<10^{-4}$ - 10^{-5} ELCR) when the water is used on a short-term basis, ORS and DWS have chosen a maximum time of three years for this exposure to continue. This value is not based on empirical dose-response relationships, but rather reflects an appraisal of the maximum amount of time that might be required to design, construct and bring into operation remediation systems. In these cases, the goal should be to strive for the shortest periods of exposure possible.

3.0 NON-DRINKING WATERS

The management of toxic chemicals in surface waters in Massachusetts focuses on the protection of public health and on the enhancement of the quality and value of the water resources in the state. These objectives are achieved through the use and derivation of concentrations of the chemicals in water that serve as guidelines. The guidelines are individual numbers generally intended to represent concentrations of the chemicals in surface waters which, acting alone, should pose no adverse health threat to humans, aquatic life or wildlife.

The Massachusetts Surface Water Quality Standards contained in the Massachusetts General Laws provides the authority for the Department of Environmental Protection (DEP) to regulate non-drinking waters. The Massachusetts Surface Water Quality Standards were last promulgated on July 20, 1990.

3.1 AQUATIC LIFE PROTECTION

3.1.1 Applicable Legislation

The Massachusetts Surface Water Quality Standards apply to all classes of fresh and salt surface waters in Massachusetts including drinking waters as well as waters designated for primary and secondary contact recreation. These Standards, contained in 314 CMR 4.00 of the Massachusetts General Laws, specify that at a minimum, all surface waters shall be free from pollutants in concentrations that are toxic to humans, aquatic life or wildlife.

Section 4.05 (5)(e)(1) of the Massachusetts Surface Water Quality Standards authorizes the Department to use the recommended pollutant-specific limits published by EPA pursuant to Section 3.04 (a)(1) of the Federal Clean Water Act, including criteria listed in Quality Criteria for Water 1986 (EPA 440/5-86-001) (i.e., EPA's "Gold Book"), to establish water quality based effluent limitations. In addition, where recommended limits are not available or are judged to be inapplicable to a particular situation due to site-specific physical, chemical or biological considerations, the Department is authorized by these regulations to use a site-specific limit which, at a minimum, should not exceed safe exposure levels determined by toxicity testing using Department-approved methods.

3.1.2 Overview

The introduction of wastewaters into surface water bodies is regulated with surface water discharge permits. The DEP Division of Water Pollution Control (DWPC) uses the EPA criteria as well as any site-specific criteria to make determinations on a case by case basis as to effluent discharge limitations for surface water discharge permits. DWPC uses a combination of recommended limits and site-specific limits to make decisions based on its perception of the pollutants of concern and the potential impacts resulting from their presence. DWPC's goals for the control of toxic pollutants in surface waters include the protection of human health, the protection of aquatic life and the prevention of bioaccumulation of toxic pollutants in sediments or biota, particularly fish and shellfish.

3.1.3 U.S. EPA Water Quality Criteria For The Protection of Aquatic Life

The U.S. EPA Water Quality Criteria for the protection of aquatic organisms are available for acute and chronic exposures to aquatic freshwater and marine organisms. The derivation of the ambient water quality criteria for the protection of aquatic life is a complex process initiated with an extensive literature review and collection of data relating to the toxicity to and bioaccumulation by aquatic organisms of the specific chemical under review. Minimum data requirements for both freshwater and saltwater are established to include information on a variety of representative species and families native to North America. Data are reviewed to eliminate studies conducted using inappropriate or invalid techniques. If data for a particular chemical are judged to be adequate, the following criteria are developed from this information:

An **acute toxicity value** is developed to represent a maximum one-hour average concentration that should not result in unacceptable effects on aquatic organisms and their uses. If appropriate, this concentration is related to a water quality parameter such as pH, salinity or hardness.

A **chronic toxicity value** is developed to represent a maximum 4-day average concentration that should not pose unacceptable toxicity during long-term exposure. If possible, this concentration is

also related to a water quality characteristic as above.

Data on toxicity to aquatic plants are reviewed to determine whether aquatic plants might be unacceptably affected at levels which are deemed acceptable to animals. Data on bioaccumulation of residues by aquatic organisms are also reviewed to determine whether concentrations of residues in edible species might exist at levels that are unacceptable to wildlife consumers of aquatic life or whether Federal Food and Drug Administration (FDA) criteria for fish are exceeded. All other available information is also reviewed to assess if there is any potential of any other adverse biological effect.

For additional detail regarding the development of these guidelines, refer to the EPA Gold Book (Quality Criteria for Water, EPA, 1986).

3.1.4 DEP Site-Specific Limits For The Protection of Aquatic Life

In the absence of EPA recommended limits, or if conditions at the site are very different from those used to develop a recommended limit or criterion, site-specific limits are determined to evaluate the threat of harmful effects to aquatic organisms. For example, site-specific limits may be established to account for some unique aspect of the local situation such as background water chemistry or the presence/absence of particular water uses. These limits should not exceed safe exposure levels derived by toxicity testing using Department-approved methods. The DWPC has established recommendations for specific tests and methodologies for the measurement of acute and chronic toxicity. These recommendations are described below.

3.1.4.1 DEP Toxicity Testing Requirements. Toxicity tests are a means by which the effects of a chemical or a complex effluent can be determined using living organisms. These tests measure the degree of response of an exposed test organism to a specific chemical or effluent. The advantages of such a test system are several: toxicity testing measures the response of organisms to a whole effluent as a mixture of chemicals, not to individual chemical constituents, permitting the assessment of additive, synergistic or antagonistic responses. The evaluation performed can be made very site-specific in that water from the site can be used for dilution, representing actual site conditions.

The DWPC guidelines for toxicity testing specify that tests for both acute and chronic toxicity be conducted using at least two species of organisms (usually a vertebrate and an invertebrate). The specific tests recommended by the DWPC are listed below.

Inland Waters

Acute Tests

- o 48-hour Ceriodaphnia dubia static test
- o 48-hour Pimephales promelas static test

Chronic Tests

- o 7-day Ceriodaphnia dubia static renewal test
- o 7-day Pimephales promelas static renewal test

Coastal and Marine Waters

Acute Tests

- o 48-hour or 96-hour Mysidopsis bahia static test
- o 48-hour or 96-hour Cyprinodon variegatus static test

Chronic Tests

- o 7-day Cyprinodon variegatus survival and growth test
- o 7-day Mennidia sp. survival and growth test
- o Arabacia punctata fertilization test
- o 7-9 day Champia parvula sexual reproduction test

The results of the most sensitive test are used to determine the toxicity criteria. For chemicals which are known to bioaccumulate, more stringent limits than those required by the toxicity testing requirements may be set.

3.1.4.2 Evaluation Methodology. The results of the toxicity testing are used to make decisions regarding discharge permit approval. The DWPC has the responsibility for evaluating and issuing National Pollution Discharge Elimination System (NPDES) permits for discharges to surface water (DWPC, February 23, 1990).

Permit approval depends upon the capacity of the receiving waters to dilute the incoming effluent to achieve acceptable levels in receiving waters. The dilution factor characterizing a body of water is determined by the flow rate of the receiving water and the flow rate of the discharge. Generally, the higher the dilution factor of the receiving water, the greater its potential to dissipate an effluent discharge.

Usually there is a transition distance where the effluent concentration is diluted to the receiving water concentration. This area is called the mixing zone. The Surface Water Quality Standards allow chronic toxicity criteria to be exceeded within mixing zones as long as there is safe and adequate passage for swimming and drifting organisms to pass through without causing deleterious effects on their populations. Since such organisms are assumed to spend only a brief period of time in the mixing zone, and will not be in the zone long enough for chronic exposure, it is assumed that exposures are of an acute nature. Therefore, under some circumstances chronic toxicity criteria may be exceeded within a mixing zone, but under no circumstances may acute toxicity criteria be exceeded within the mixing zone. Outside of the mixing zone, both acute and chronic toxicity criteria apply.

Calculation of receiving water concentrations outside of the mixing zone is conducted using dilution factors and assuming completely mixed conditions.

To evaluate a discharge in terms of aquatic life protection, the DWPC identifies and defines several parameters:

- NOEC** - No Observed Effect Concentration: the highest measured continuous concentration of an effluent that causes no observed acute or chronic effect on a representative standard test organism.
- RWC** - Receiving Water Concentration: At critical conditions, the NOEC measured in percent must be greater than or equal to the RWC of effluent in percent by volume ($\text{NOEC} \geq \text{RWC}$).
- LC50** - The concentration of a substance (measured in percent for effluents) that is lethal to 50% of the test organisms; represents the degree of toxicity on an inverse logarithmic scale; is usually associated with an exposure time (e.g., 24, 48, 96 hours).
- T.U.** - Toxic Unit: $\text{T.U.} = (100/\text{LC50})$
- critical conditions** - for inland rivers and streams: the lowest average flow for seven consecutive days to be expected once in ten years (7Q10)

- for lakes, ponds and marine waters:
established case-by-case

dilution factor - (the dilution available to a particular effluent): the ratio of the receiving water flow (Q_r) plus the effluent flow (Q_e) to the effluent flow

$$\text{dilution factor} = \frac{Q_r + Q_e}{Q_e}$$

The DWPC has established a policy for regulating toxic chemicals in surface waters entitled the "Massachusetts Water Quality Standards Implementation Policy for the Control of Toxic Pollutants in Surface Waters." This policy establishes the following guidelines: The recommended limit to prevent against acutely toxic effects is 0.3 T.U. This value is based on an adjustment factor of one-third used to extrapolate the LC50 to an LC1 (concentration at which 1% of the test organisms die). In addition, the DWPC has established an end-of-pipe limit of 1.0 T.U. for dilution factors less than or equal to 100 and 2.0 T.U. for dilution factors greater than 100.

At dilution factors less than 10, effluent toxicity poses a high risk to receiving waters. These waters are considered water quality limited in that the effluent limit of 1.0 Toxic Unit may not be stringent enough to protect receiving waters. The Division requires both acute and chronic endpoints to be reported. Two limits apply to the effluent: 1) the chronic test should result in a No Observed Effect Concentration greater than or equal to the Receiving Water Concentration ($\text{NOEC} \geq \text{RWC}$) and 2) the acute level should be less than or equal to 1.0 Toxic Unit (an $\text{LC}_{50} \geq 100\%$).

Dilutions from 10 - 100 have an effluent limit of 1.0 Toxic Unit. In the lower portion of this range (from 10 - 20) waters may be water-quality limited if the specific toxicants involved have high acute to chronic ratios. Therefore, the Division requires chronic monitoring to assure that the effluent limitation is adequate. In the range of dilution from 20 - 100 chronic monitoring is not required. Waters with dilutions above 100 have an effluent limit of 2.0 Toxic Units.

Recommended methods for toxicity testing are presented in Table 3.1. Generally, the Division requires four (4) samples per year at dilutions less than or equal to 100. Each sample is tested with two (2) test species. At dilutions greater than 100, two samples per year are required."

TABLE 3.1. WHOLE EFFLUENT TOXICITY REQUIREMENTS FOR NPDES PERMITS

DILUTION FACTOR	EFFLUENT LIMITS	TESTING REQUIREMENTS
< 10	NOEC \geq RWC 1.0 Toxic Unit	4 samples/year; 2 species; Acute and chronic endpoints
10 - 20	1.0 Toxic Unit	4 samples/year; 2 species; Acute and chronic endpoints
> 20 - 100	1.0 Toxic Unit	4 samples/year; 2 species; Acute endpoint
> 100	2.0 Toxic Unit	2 samples/year; 2 species; Acute Endpoint.

Notes: 1 Ratio of receiving water plus effluent flow to effluent flow at critical conditions:

$$\frac{Q_r + Q_e}{Q_e} = \text{dilution factor}$$

- 2 Effluent limits apply to the total toxicity concentration prior to mixing with receiving water. Limits are in Toxic Units where:

$$\frac{100}{LC50} = \text{Toxic Units}$$

and LC50 = Concentration lethal to 50% of the test organisms

3.2 HUMAN HEALTH PROTECTION

3.2.1 Fish Ingestion

3.2.1.1 Applicable Legislation. The Massachusetts General Laws pertaining to Surface Water Quality Standards (314 CMR 4.00) grant the Massachusetts Department of Environmental Protection (DEP) the authority to regulate surface water quality.

1.) Within that authority, section 314 CMR 4.05 (5)(e) of the Massachusetts General Laws gives DEP the authority to use United States Environmental Protection Agency (EPA) Ambient Water Quality Criteria (AWQC) as guidance in establishing discharge limits for surface water for individual pollutants not specifically listed in the regulations.

2.) In the absence of an EPA-recommended limit for a specific pollutant or in cases where existing limits are considered invalid due to site-specific physical, chemical or biological considerations, the Division shall use a site-specific limit. Guidance for establishing site-specific limits shall at a minimum not exceed safe exposure levels determined by toxicity testing using methods approved by the Director of the Division of Water Pollution Control (DWPC) (4.05(5)(e)(1)).

3.) Furthermore, 314 CMR 4.05 (5)(e)(2) specifies that human-health based guidance concentrations for drinking water be issued by the DEP Office of Research and Standards (ORS) with the goal of eliminating " . . . within the limits of practicability and feasibility, all adverse effects which may result from the ingestion of, inhalation of or dermal contact with contaminated water."

4.) In addition, section 314 CMR 4.05 (5)(e)(3) specifies that where appropriate the Department shall use an additional margin of safety when establishing water-quality based effluent criteria "to assure that pollutants do not persist in the environment or accumulate in organisms to levels that: (a) are toxic to human or aquatic life; or (b) result in unacceptable concentrations in edible portions of marketable fish or shellfish or for the recreational use of fish, shellfish, other aquatic life or wildlife for human consumption."

The State uses a combination of approaches described below for assessing the toxicity of chemicals in fish to humans including the use of EPA Ambient Water Quality Criteria, the federal Food and Drug Administration (FDA) action levels and tolerances as well as health risk assessment.

3.2.1.2 Overview. Primary responsibility for regulating the safety of foods including fish in Massachusetts and for issuing fish consumption advisories resides with the Massachusetts Department of Public Health (DPH). Nevertheless, DEP's Office of Research and Standards (ORS) is often asked to review results of fish contaminant monitoring studies conducted in Massachusetts to provide DEP with information on potential health risks. This information is used by DEP to control water quality.

The evaluation of fish contaminant data by ORS is a relatively new function of the office. The methodologies for evaluating these data are evolving. The protocol described in this section is therefore subject to refinement over time to reflect improvements in the methodology.

The ORS evaluation of the human health hazard posed by toxic chemicals in fish includes three separate components:

1.) **Comparison to Criteria Concentrations Calculated from U.S. EPA Ambient Water Quality Criteria and to ORS Guidelines** - The first component uses U.S. EPA criteria or ORS guidelines by comparing reported concentrations of chemicals in fish tissue to criteria concentrations of the chemicals in fish as back-calculated from applicable EPA Ambient Water Quality Criteria (AWQC) for protection of human health via fish ingestion;

2.) **Comparison to U.S. FDA Criteria for Fish Ingestion** - The second component involves a comparison of detected concentrations of contaminants in fish tissue to applicable action levels and tolerances developed by the FDA;

3.) **Risk Assessment from Fish Ingestion** - The third component is an evaluation methodology, similar to the methodology used to assess chemically contaminated drinking waters, for determining the human health risk when chemicals are present in fish tissue either singly or in combination. These three evaluation methods are all used by ORS to characterize health risks more completely and each is described in the following sections.

3.2.1.3 Comparison to Criteria Concentrations Calculated from U.S. EPA Ambient Water Quality Criteria and to ORS Guidelines.

A. Ambient Water Quality Criteria for the Protection of Human Health

The EPA Ambient Water Quality Criteria (U.S. EPA, 1986) for protection of human health are available for two exposure

scenarios. The AWQC are estimates of the surface water concentrations that will not result in adverse health effects in humans exposed to chemicals through one of two exposure scenarios. One exposure scenario considers ingestion of drinking water and aquatic organisms. The other exposure scenario considers only ingestion of aquatic organisms. ORS uses the criteria developed using the latter exposure considerations, ingestion of aquatic organisms only, for its fish toxics evaluations.

The exposure assumptions inherent in these criteria are that an individual with a lifetime average body weight of 70 kg consumes an average of 6.5 g of aquatic organisms daily for a 70-yr lifetime. For noncarcinogens, EPA applies standard exposure assumptions to an EPA RfD to derive acceptable daily doses. Bioconcentration factors for chemicals from water into fish are then used to calculate the AWQC concentrations in water. For carcinogens, EPA specifies a recommended water concentration of zero for the maximum protection of human health. However, EPA provides estimates of water concentrations corresponding to increased lifetime cancer risks of 1×10^{-7} , 1×10^{-6} and 1×10^{-5} .

DEP uses AWQC concentrations with bioconcentration factors to calculate Criteria Concentrations of toxic chemicals in fish tissue. For carcinogens, DEP uses the AWQC concentration corresponding to an Estimated Lifetime Cancer Risk (ELCR) of 1×10^{-6} .

B. DEP Criteria Concentrations for Fish Calculated from AWQC

In order to use the AWQC in the evaluation of fish toxics monitoring data, an estimate is made of the equilibrium concentration existing in the fish corresponding to the concentration in water at the AWQC level.

This is done using the following relationship:

$$[\text{Cont}]_{fi} = \text{BCF}_{fish} * [\text{Cont}]_w * \text{UCF}$$

where:

- $[\text{Cont}]_{fi}$ = Criteria Concentration of a contaminant in fish (dimensions: mass/mass)
- BCF_{fish} = Fish bioconcentration factor (ratio of the contaminant concentration in fish to the contaminant concentration in water)
- $[\text{Cont}]_w$ = Concentration of a contaminant in water

at the AWQC (dimensions: mass/volume)

UCF = unit conversion factor for water: 1 L/kg.

This equation indicates that the fish tissue concentration of a compound is a function of the water concentration and of the fish Bioconcentration Factor (BCF) for that compound. BCFs are derived quantitatively by dividing the concentration of a material in one or more tissues of an aquatic organism by the average concentration in the solution in which the organism had been living. A BCF is intended to account only for net uptake directly from the water. The BCFs used by the EPA for deriving AWQC are presented and discussed in the EPA Ambient Water Quality Criteria documents for individual chemicals. BCF values for the same chemical can vary greatly between species of fish based on such factors as fish metabolic rate, excretion rate, stage of life cycle and lipid content. As a result, ORS will review the origin and basis for the BCF for a particular chemical used by EPA in the derivation of AWQC on a case-by-case basis to determine whether it is applicable to the particular situation being evaluated by ORS.

The fish tissue Criteria Concentrations serve as guidelines. An evaluation using these criteria involves a comparison of detected concentrations of compounds in fish to the respective guideline level calculated above for that chemical.

For chemicals for which AWQC do not exist, ORS may develop its own guidelines, based on the availability of adequate toxicity data (i.e., EPA Reference Doses and Cancer Potency Factors). The same assumptions as those used by EPA for developing the AWQC are used. Thus the ORS guidelines assume that an individual with an average body weight of 70 kg ingests contaminated fish for a period of 70 yrs. However, to be consistent with its guideline-derivation policies in other media, ORS makes several refinements to the methodology used by EPA to develop AWQC.

ORS develops guidelines for both average and maximum fish ingestion rates. The average ingestion rate assumed is 6.5 g/day, the same rate used by EPA in developing the AWQC. The maximum ingestion rate assumed is 132.0 g/day, based upon a study of fish ingestion rates by Foran et al., 1989 for freshwater fish. The two criteria are used to apply to scenarios involving very different frequencies of fish ingestion, from individuals who consume about 1-2 fish meals per month to those who do subsistence-type fishing and may eat fish nearly every day (i.e., 18-27 meals per month).

In addition, the ORS guidelines consider both carcinogenic and noncarcinogenic effects. EPA instead develops one AWQC number for an individual compound based on either carcinogenic or noncarcinogenic effects. EPA's methodology to derive AWQC does

not account for both types of effects. Thus an AWQC based on threshold effects is not developed for a compound that is also carcinogenic. The ORS methodology on the other hand, develops a guideline based on carcinogenic effects and a separate guideline based on noncarcinogenic effects, and then chooses the lower of the two as the criteria concentration.

The ORS calculation may also include a relative exposure contribution (REC) factor for exposure via fish ingestion. A REC is a factor which is often applied in risk assessment calculations to estimate the percent contribution of a contaminant via a particular medium to total exposure. ORS has developed a preliminary methodology to develop relative exposure contribution factors for fish ingestion relative to total ingestion exposure. Since the toxicity assessment from ingestion of fish is ultimately based on oral Reference Doses (RfD) and since the REC is to be expressed as a percent of the RfD, RECs are being developed considering only ingestion exposures. This approach is in contrast to the EPA approach used in developing drinking water guidance which applies a relative source contribution factor of 20% to the oral RfD to account for the assumption that 20% of total exposure to a particular compound comes from drinking water exposures. In the absence of adequate exposure data for a chemical, ORS will use a default value of 20% as the REC. A preliminary methodology for deriving contaminant-specific fish relative exposure contribution factors is being developed by ORS.

A Bioavailability Adjustment Factor (BAF) is also included in the equation to account for differences in absorption efficiencies of contaminants via fish ingestion and via the exposure route used by EPA to derive the Reference Dose (RfD). In this way, the detected contaminant concentrations in fish can be more appropriately compared to the developed guideline.

Finally, the assumptions inherent in the AWQC are based on the average adult. Exposures by children are not considered. The ORS methodology allows for the development of guidelines based upon the parameters for a child. On an as-needed basis, adjustments can also be made to the AWQC to account for specific exposures involving children.

The following relationships describe the derivation of the ORS guidelines, based on noncarcinogenic and carcinogenic effects:

for noncarcinogenic effects:

$$CC_{\text{fish}} = \frac{REC_{\text{fish}} * RfD * BAF * BW}{IR_{\text{fish}}}$$

where:

CC_{fish}	=	Criteria Concentration in fish tissue (dimensions: mass/mass)
REC_{fish}	=	Relative Exposure Contribution factor via fish ingestion (contaminant-specific)
RfD	=	EPA Reference Dose (dimensions: mg/kg/day)
BAF	=	Bioavailability Adjustment Factor
BW	=	average body weight of a human adult (70kg)
IR_{fish}	=	fish ingestion rate (6.5 g/day)

* For a child an appropriate body weight should be used:
(i.e., BW = 20 kg)

for carcinogenic effects:

$$CC_{fish} = \frac{REC_{fish} * (1 * 10^{-6}/CPF) * BW}{IR_{fish}}$$

where:

CC_{fish}	=	Criteria Concentration in fish tissue dimensions: mass/mass)
REC_{fish}	=	Relative Exposure Contribution factor via fish ingestion (contaminant-specific)
CPF	=	EPA Cancer Potency Factor (dimensions: (mg/kg/day) ⁻¹
BAF	=	Bioavailability Adjustment Factor
BW	=	average body weight of a human adult (70 kg)

$$IR_{\text{fish}} = \text{fish ingestion rate (6.5 g/day)}$$

The lower of the above two guidelines based on carcinogenic or noncarcinogenic effects is selected as the ORS guideline. Thus the ORS guideline is based on the most sensitive effect and accounts for both effects.

As fish toxics evaluations are conducted and the criteria concentrations and guidelines discussed above are developed, a list of these criteria will be compiled by ORS.

An evaluation of potential human toxicity involves a comparison of detected contaminant concentrations in fish to the above criteria. In cases where all chemical concentrations are less than their respective guideline values, it may be judged that ingestion of the fish being evaluated may pose no unacceptable human health hazard. However, a comparison to FDA criteria for those compounds for which these criteria exist is also made. In addition, because the AWQC may not be based on the most current toxicological data and because the cumulative exposure to mixtures of chemicals is important to evaluate, a risk analysis is also performed.

3.2.1.4 Comparison to U.S. FDA Criteria for Fish Ingestion. The Food and Drug Administration (FDA) issues a list of legal action levels and tolerance values for a limited number of chemicals which apply to fish oil or to the edible portion of fish and shellfish in interstate commerce.

FDA criteria are generally set as a result of a risk-balancing process. The economic costs and loss of dietary benefits from fish ingestion associated with more stringent regulations for the recreational and commercial fisheries in the U.S. are weighed against the severity of possible health effects of a particular chemical. As a result, the health risks associated with the FDA criteria values may be higher than target risk levels used as goals for acceptability within the Department of Environmental Protection.

Evaluation using FDA numbers involves a comparison of detected concentrations of compounds in fish tissue to FDA criteria. Even in cases where all compound concentrations are below FDA criteria, health risks may be unacceptable to the state. This situation results from the fact that FDA criteria are not solely health-based. The availability of FDA criteria for a limited number of chemicals also limits their usefulness.

3.2.1.5 Risk Assessment for Fish Ingestion.

A. Description of Approach

As with the evaluation of drinking water, ORS uses a risk assessment approach for evaluating public health risks from fish ingestion. The assessment addresses both threshold-type and nonthreshold-type effects and evaluates the degree of human health hazard posed by individual chemical contaminants as well as that posed by mixtures of contaminants. To assess the potential for threshold effects, a Hazard Index is calculated as discussed in Section 2.3.5. ORS' current policy regarding mixtures is to use a dose additive model to assess the additive effects of a mixture's individual components. As discussed previously, dose addition is not the most biologically plausible approach if the compounds do not have the same mode of toxicologic action. Thus separate hazard indices are calculated for compounds which produce similar toxicologic effects. To assess nonthreshold effects, the Estimated Lifetime Cancer Risk (ELCR) is calculated for the theoretical individual who spends his/her lifetime ingesting contaminated fish. The toxicologic endpoint of concern in this case is only one: cancer. The four-step risk assessment process (described in section 2.3.3 - Risk Assessment of this document) including hazard identification, dose-response assessment, exposure assessment and risk characterization is followed.

B. Calculation of Average Daily Dose

Although the EPA AWQC discussed in 3.2.1.2 are also based on EPA toxicity values (RfDs and cancer potencies), the toxicological values used in developing the AWQC may not be the most current. The risk analysis approach is more flexible because it permits consideration of a range of ingestion rates, as contrasted with the national average fish consumption rate used in the derivation of AWQC.

The estimation of the Average Daily Dose (ADD) of a chemical that an individual receives through ingestion of fish is only one component of the assessment of the health hazard of a chemical. The general equation used to estimate the daily dose is expressed as:

$$\text{ADD}_{fi} = \frac{[\text{Cont}]_{fi} * \text{IR} * \text{BAF} * \text{D}_2 * \text{C}}{\text{BW}_{\text{avg}} * \text{AP}}$$

where:

$[Cont]_{fi}$	=	Representative concentration of contaminant in fish (dimensions: mass/mass)
IR	=	Daily fish ingestion rate (dimensions: mass/time)
BAF	=	Bioavailability Adjustment Factor
D_2	=	Duration of the exposure period (dimension: time)
C	=	Appropriate units conversion factor(s)
BW_{avg}	=	Average body weight of the receptor of concern during the averaging period (dimension: mass)
AP	=	Averaging Period (dimension: time)

In the above equation, the concentration of contaminant in fish tissue ($[cont]_{fi}$) should ideally be representative of the edible portion of the fish. However, when these data are unavailable, information on whole fish concentrations can be used.

In addition, where data are available for a particular site, the above estimate can be refined further by considering two additional factors. These are: 1.) the **Cooking Loss factor (CD)** - This factor is defined as the proportion of toxic contaminants remaining in the fish after cooking: this type of data is usually obtained from individual studies designed for this purpose; and 2.) the **Local Consumption factor (LC)** - This factor is defined as the percent total fish consumption in an area which is derived from local recreational stock. When available, the LC is used to further characterize the nationally or regionally derived fish ingestion rate. The data represented by both of these factors are not typically available but will be used when possible to refine the estimate.

Finally, this equation reflects the basic calculation to estimate the average daily dose used in assessing noncarcinogenic effects. To calculate the Lifetime Average Daily Dose (LADD) used for assessing carcinogenic risks, the averaging period (AP) above is assumed to be 70 yrs and the duration of the exposure period is also assumed to be 70 yrs.

C. Methods to Assess Hazard

The Hazard Index: Comparison of ADD_{fi} with RfD

The likelihood of potential non-cancer threshold-type health effects posed by a mixture of chemicals is evaluated with the hazard index approach, described in detail in Section 2.3.5. The ADD for each chemical is divided by its respective RfD and then these ratios can be summed to provide an estimate of the likelihood of threshold-type health effects for the mixture of chemicals in fish. A separate hazard index should be generated for each toxicologic endpoint of concern (i.e., with the same mechanism of toxicologic action).

Non-Threshold Effects Evaluation

The risks associated with non-threshold health effects (i.e., carcinogenesis) are characterized by focussing on estimated ELCR, described in detail in Section 2.3.6, for the theoretical individual who ingests contaminated fish for a lifetime. The total ELCR is calculated by summing the individual ELCR for each chemical existing in the fish.

D. Risk Management Criteria

ORS' policy for managing risk is to try to achieve a situation in which no significant risk of harm to human health, public welfare, safety or the environment exists. However, site-specific and other factors may make attainment of this goal infeasible. ORS therefore sets the following guidelines for evaluating risks:

Hazard Index (Threshold Effects)

For evaluation of fish toxicity, a total HI greater than 1.0 indicates the possibility of threshold (noncarcinogenic) effects resulting from longer term ingestion of fish. A total HI less than or equal to 1.0 indicates that threshold effects would not be expected to occur as a result of exposure to contaminated fish for any period of time. Based on the risks calculated, fish consumption advisory levels (using the same exposure assumptions) may be developed which specify the amount of fish that can be ingested safely, if any, without exceeding a defined level of risk.

Non-Threshold Effects

ORS generally considers a total ELCR greater than 1 in 10,000 (1×10^{-4}) to be an unacceptable risk, a total ELCR greater than 1 in 100,000 yet less than 1 in 10,000 ($1 \times 10^{-4} > \text{ELCR} > 1 \times 10^{-5}$) to

be an unacceptable risk for long-term exposure, and a total ELCR less than 1 in 100,000 (1×10^{-5}) to be an acceptable risk.

As specified above, for exposure through fish ingestion, fish consumption advisory levels may be determined through risk analysis to specify the amount of contaminated fish that can be ingested in order to remain within a defined range of risk.

DEP also strives to be consistent in its application of risk management criteria across media or in different situations. Fulfillment of this objective when evaluating contaminants in fish is complicated by the facts that: some contaminants (e.g., PCBs) have widespread distributions and often occur in high concentrations in fish in the state; and ingestion of fish confers a nutritional benefit.

3.2.1.6 Implications of Multiple Assessment Methodologies/Policy Development. Use of a multiple assessment methodology as described above permits evaluation of the hazard to humans from eating contaminated seafood products from several perspectives. No one method of evaluation has been chosen consistently over the others.

The FDA criteria generally permit a higher body burden of contaminant in fish tissue than would be derived by the other two methods. These criteria are available for only a few chemicals which limits the scope of their usefulness. In addition, the criteria have been developed to apply to fish in the marketplace and they reflect the fact that the average consumer probably receives his/her fish from a variety of sources and some higher concentrations of contaminants in some fish bought by that consumer will probably be offset by lower concentrations in other fish from the marketplace. On the other hand, recreational and subsistence fishermen who may derive a large part of their diet from fish from one localized area may not be adequately protected by these criteria. DEP is usually faced with evaluating the hazards posed to the public as a result of localized contamination, rather than evaluating fish in the marketplace.

As a result of the way in which FDA criteria are set, the human health hazard posed to some consumers as a result of ingesting fish with some contaminants at the FDA action level is greater than the Department would normally allow under other circumstances.

Criteria concentrations calculated from U.S. EPA Ambient Water Quality Criteria for fish ingestion present greater flexibility for assessment of site-specific related health risks. Carcinogenic and non-carcinogenic health effects, the relative magnitudes of doses

received from fish versus other sources of exposure to the chemical and exposures to children can be taken into consideration. It is however recognized that the EPA criteria were derived several years ago and may not therefore contain the most current estimates of the toxicological action of some chemicals.

A risk assessment provides all the flexibility of the Criteria Concentrations, plus it permits the use of the most current toxicological data. Both estimates of chemical hazard derived through risk assessment and from AWQC are health-based numbers. The FDA criteria include consideration of other factors.

Final judgement on degree of health risks and management of those hazards is made after consideration of the nature of the population exposed, their likely fish consumption patterns and the background concentrations of the chemicals in fish in the state. There are certain chemicals which are widely distributed in freshwater fish tissues within Massachusetts which generally are at or below the respective FDA Criteria concentrations for those chemicals, but which pose unacceptable health risks if judged by the Department's risk management criteria. In instances such as this, ORS would try to determine if any particular species or age of fish had greater concentrations of the contaminant and then work with DPH to focus advisories on those species or size of fish. Historically, DPH has employed FDA Criteria as the evaluation standard for determining human health hazards from contaminated fish. ORS and DPH are working to improve the methodologies described above for assessing these risks and to integrate them into the Department's risk management framework.

3.2.2 Secondary Contact Evaluation

Exposures to chemicals in surface waters not used as drinking water may occur as a result of the following processes:

- (1) incidental ingestion of surface water while swimming;
- (2) dermal contact with surface water; and
- (3) inhalation of chemicals that have volatilized from surface water.

Typically, concentrations of volatile organic compounds (VOCs) in surface water bodies are relatively low due to their volatile nature and because of the large mixing volumes of water. In such cases, the relative risks from the dermal absorption and inhalation routes of exposure are often minor and insignificant compared to possible incidental ingestion exposures to contaminated surface water.

When ORS believes that secondary contact exposures could be significant routes of toxicity, the exposures are generally evaluated by the equations presented below.

The Average Daily Dose received by an individual via contaminated surface water (ADD_{sw}) is the sum of the ADDs for exposures resulting from incidental ingestion of the surface water (ADD_{swi}), dermal contact with the contaminated surface water (ADD_{swd}), and inhalation of chemicals volatilized from the surface water (ADD_{swih}).

$$ADD_{sw} = ADD_{swi} + ADD_{swd} + ADD_{swih}$$

3.2.2.1 Incidental Ingestion of Contaminated Surface Water.

Intakes from incidental ingestion of surface water may happen while swimming in and during recreational use of a surface water body. The Average Daily Dose received via incidental ingestion of contaminated surface water (ADD_{swi}) may be calculated using the equation presented for the ingestion of contaminated drinking water (ADD_{dwi}) (Section 2.3.4).

3.2.2.2 Dermal Contact With Contaminated Surface Water. Dermal contact with contaminated surface water may occur while wading, swimming, or during recreational use of surface water. The Average Daily Dose received via dermal absorption with contaminated surface water (ADD_{swd}) may be estimated by the following equation:

$$ADD_{swd} = \frac{[Cont]_{sw} * SA * PC * BAF * F * D_1 * D_2 * C}{BW_{avg} * AP}$$

Where:

$[Cont]_{sw}$ = Representative concentration of contaminant in the surface water during the period of exposure (dimensions: mass/volume)

SA	=	Skin surface area in contact with the surface water during the period of exposure (dimension: area)
PC	=	Permeability Constant (dimensions: volume/time*area)
BAF	=	Bioavailability Adjustment Factor
F	=	Number of exposure events during the exposure period divided by the number of days in the exposure period (dimensions: events/time)
D ₁	=	Average duration of each exposure event (dimensions: time/event)
D ₂	=	Duration of the exposure period (dimension: time)
BW _{avg}	=	Average body weight of the individual exposed during the averaging period (dimension: mass)
AP	=	Averaging period (dimension: time)
C	=	Appropriate units conversion factor(s)

3.2.2.3 Inhalation of Contaminants Volatilized from Surface Water.

Individuals may be exposed to chemicals in air by inhalation of chemicals in the vapor phase above contaminated surface water. The Average Daily Dose received via inhalation of chemicals volatilized from contaminated surface water (ADD_{swih}) may be estimated by using the equation presented for inhalation of chemicals volatilized from drinking water (ADD_{dwh}) in Section 2.3.4.

4.0 REFERENCES

- Andelman, J.B. 1985. Inhalation exposure in the home to volatile organic contaminants in drinking water. *The Science of the Total Environment*. 47: 443-460.
- Brown, H.S., D.R. Bishop, and C.A. Rowan. 1984. The role of skin absorption as a route of exposure for volatile organic compounds in drinking water. *American Journal of Public Health*. 74: 479-484.
- Hennekens, C.H. and J.E. Buring. 1987. *Epidemiology in medicine*. Little, Brown and Co., Boston. 383pp.
- Massachusetts Department of Environmental Protection. 1989. Chemical health effects assessment methodology and method to derive allowable ambient limits. V. I and II. Office of Research and Standards. Report No. 90-1. May. Boston, MA.
- New Jersey Drinking Water Quality Institute. 1987. Maximum contaminant level recommendations for hazardous contaminants in drinking water. Appendix B. Health-based maximum contaminant level support documents. Report for New Jersey Dept. of Environmental Protection.
- Shehata, A.T. 1985. A multi-route exposure assessment of chemically contaminated drinking water. *Toxicology and Public Health*. 1: 277-298.
- U.S. Environmental Protection Agency. 1985. National primary drinking water regulations; synthetic organic chemicals, inorganic chemicals, and microorganisms. *Federal Register* 50 (219): 46936 - 47025.
- U.S. Environmental Protection Agency, Office of Toxic Substances. 1985. Methods for assessing exposure to chemical substances in drinking water. Methods for assessing exposure to chemical substances. Vol.5., Washington D.C., August, 1985.
- U.S. Environmental Protection Agency. 1987. National primary drinking water regulations; synthetic organic chemicals; monitoring for unregulated contaminants. *Federal Register* 52: 25690-25717/July 8.
- U.S. Environmental Protection Agency. 1989. National primary and secondary drinking water regulations; proposed rule. *Federal Register* 54:22062-22160/May 22.
- Vanderslice, R. n.d. Estimates of dermal absorption of drinking water contaminants. Unpublished manuscript. U.S. EPA Office of Drinking Water.
- Wisconsin Department of Health and Social Services. 1988.

Recommended public health related groundwater standards - 1986.
Summary of scientific support documentation for NR 140.10.



The Commonwealth of Massachusetts
Executive Office of Environmental Affairs
Department of Environmental Protection
Office of Research and Standards

